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MATT BLUNT SECRETARY OF STATE

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Missouri



REGISTER

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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at http://www.sos.mo.gov/adrules/pubsched.asp

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RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 26, *Missouri Register*, page 27. The approved short form of citation is 26 MoReg 27.

The rules are codified in the Code of State Regulations in this system—

TitleCode of State RegulationsDivisionChapterRule1CSR10-1.010DepartmentAgency, DivisionGeneral area regulatedSpecific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division in the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—Cite material in the RSMo by date of legislative action. The note in parentheses gives the original and amended legislative history. The Office of the Revisor of Statutes recognizes that this practice gives users a concise legislative history.

FROM THIS ANGLE...

Telephone Calls . . . this summer

Over the summer, please expect to receive a telephone call from a member of the Administrative Rules editorial staff seeking your help in updating our records. We will want to know the contact person or persons for your agency for rulemaking purposes (both for content and data entry), mailing address, telephone numbers, e-mail addresses and any other pertinent information for your agency. We will also ask if there are any changes in your staffing insofar as Directors and delegation of authority as to whom signature authority extends for your agency and whether the signatures we currently have on file are correct. Absent the correct signatures we cannot permit your agency to file rulemakings with our office.

We will also be requesting your agency review your rules as they currently appear in *Code*. Many agencies have old rules, which are no longer being enforced, old rules, which need to be updated, amended, rescinded, or rulemakings, which should be totally removed from *Code*. Many agencies also have old out-of-date forms, which need to be removed from *Code*. Only your agency can update or change what currently appears in *Code*. To remove an old form, it takes an action from your agency. Our office cannot remove those without action by your agency. We are attempting to clean up the *Code of State Regulations* so that we can accomplish many things—having a totally verified text for automation purposes, alleviating the overstuffed pages in the binders, and keeping *Code* current, just to name a few. Please be responsive to the Editors when they call seeking your assistance with these matters.

Suggestion on updating forms

Many agencies have adopted our suggestion for one manner of keeping your forms in *Code* current. We suggest your agency consider adding a website reference which refers the reader to your website for the most current downloadable, fillable form for their use. This accomplishes two things – it keeps your rules in *Code* current and the form utilized for

your agency is the most current version. If you need assistance with this suggestion, please contact our main line number at 573-751-4015.

New Web Address - Please change your "Favorites"

The Secretary of State's web address has changed. Please change your "favorites" to reflect this change as follows: www.sos.mo.gov. If you wish to access Administrative Rules directly, please add the designation /adrules after gov (www.sos.mo.gov/adrules).

As always, please advise if we may be of any assistance to you in the rulemaking process – anything from numbering questions, to format questions, to rulemaking classes, at your office or ours – we're always glad to help.

Lynne C. Angle

Director, Administrative Rules

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Inder this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

ntirely new rules are printed without any special symbology under the heading of the proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

n important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register*. If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

n agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety (90)-day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder: **Boldface text indicates new matter**.

[Bracketed text indicates matter being deleted.]

Title 2—DEPARTMENT OF AGRICULTURE Division 30—Animal Health Chapter 9—Animal Care Facilities

PROPOSED AMENDMENT

2 CSR 30-9.020 Animal Care Facility Rules Governing Licensing, Fees, Reports, Record Keeping, Veterinary Care, Identification and Holding Period. The director is adding the following new subsections (1)(T) and (14)(G), new subparagraph (11)(B)1.I., removing paragraphs (13)(B)2. and (15)(C)3.

PURPOSE: This proposed amendment sets forth requirements to document the disposition of animals handled by animal rescues and shelters

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material, which is incorporated by reference as a portion of this rule, would be unduly cumbersome

or expensive. Therefore, the material, which is so incorporated, is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material. The publication for 2000 Report of the AVMA Panel on Euthanasia can be asscess at http://www.avma.org.

(1) Application For License and Conditions of Issuing.

(T) Contested cases and other matters involving licensees and the director, or his designee, may be informally resolved by consent agreement, settlement, stipulation, consent order, or default.

(11) Records.

- (B) Records of Operators of Auction Sales and Brokers.
- 1. Every broker or operator of an auction sale shall make, keep and maintain records or forms which fully and correctly disclose the following information concerning each animal sold, whether or not a fee or commission is charged:
- A. The name and complete mailing address of the person who owned or consigned the animal(s) for sale;
- B. The name and complete mailing address of the buyer or consignee who received the animal;
- C. The USDA and ACFA license or registration number of the person(s) selling, consigning, buying or receiving the animals if s/he is licensed or registered under the Acts;
- D. The vehicle license number and state and the driver's license number and state of the person, if s/he is not licensed or registered under the Acts;
 - E. The date of the consignment;
- F. The official USDA or ACFA tag number assigned to the animal(s) under this rule;
 - G. A description of the animal(s) which shall include:
 - (I) The species and breed or type;
 - (II) The sex of the animal;
 - (III) The date of birth or approximate age; and
 - (IV) The color and any distinctive markings; [and]
- H. The auction sales number or records number assigned to the animal/./; and
- I. The name, mailing address, any USDA/ACFA license numbers of all people registering at the auction to buy animals.

(13) Holding Period.

- (B) Any live dog or cat acquired by a commercial breeder, dealer, exhibitor or pet shop shall be held under his/her supervision and control, for a period of not less than five (5) full days, not including the day of acquisition, after acquiring the animal, excluding time in transit; provided, however—
- 1. That any live dog or cat acquired by a commercial breeder, dealer, exhibitor or pet shop from any private or contract animal pound, animal shelter, pound or dog pound shall be held by that commercial breeder, dealer, exhibitor or pet shop for a period of not less than ten (10) full days, not including the day of acquisition, after acquiring the animal, excluding time in transit;
- [2. Dogs and cats which have completed a five (5)-day holding period with another licensee or a ten (10)-day holding period with another licensee following release from an animal shelter, pound or dog pound, may be sold or otherwise disposed of by subsequent licensees after a minimum holding period of twenty-four (24) hours by each subsequent licensee excluding time in transit.]
- (14) Miscellaneous.

- (F) Handling of Animals.
- 1. Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm or unnecessary discomfort.
- 2. Physical abuse shall not be used to train, work or otherwise handle animals.
- 3. Deprivation of food or water shall not be used to train, work or otherwise handle animals; provided however, that the short-term withholding of food or water from animals by exhibitors is allowed by this rule as long as each of the animals affected receives its full dietary and nutrition requirements each day.
- 4. During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and to the public, with sufficient distance or barriers, or both, between the animal and the general viewing public so as to assure the safety of animals and the public.
- A. Performing animals shall be allowed a rest period between performances at least equal to the time for one (1) performance.
- B. Young or immature animals shall not be exposed to rough or excessive public handling or exhibited for periods of time which would be detrimental to their health or well-being.
- C. Drugs, such as tranquilizers, shall not be used to facilitate, allow or provide for public handling of the animals.
- D. Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.
- E. A responsible, knowledgeable and readily identifiable employee or attendant must be present at all times during periods of public contact.
- F. During public exhibitions, dangerous animals such as lions, tigers or wolves must be under the direct control and supervision of a knowledgeable and experienced animal handler.
- G. If public feeding of animals is allowed, the food must be provided by the animal facility and shall be appropriate to the type of animal and its nutritional needs and diet.
- 5. All euthanasia of animals shall be accomplished by a method approved by the [1993] 2000 edition, or later revisions, of the American Veterinary Medical Association's Pan on Euthanasia, as incorporated by reference in this rule.
- (G) When foster homes are used to house animals at locations other than an animal shelter, the licensee must annually provide a listing of names, addresses and phones for all active fostering sites.
- (15) Procurement of Dogs and Cats By Licensees.
- (C) Any licensee or exhibitor who also operates a public or private pound, animal shelter, contract pound, pound or dog pound shall comply with the following:
- 1. The animal pound or shelter shall be located on premises that are physically separated from all other licensed facilities. The animal housing facility of the pound or shelter shall not be adjacent to any other licensed facility.
- 2. Accurate and complete records shall be separately maintained by the licensee and by the pound or shelter. All records shall be in accordance with those specified in this rule. If the animals are lost or stray, the pound or shelter records shall provide:
 - A. An accurate description of the animal;
- B. How, where, from whom and when the dog or cat was obtained:
- C. How long the dog or cat was held by the pound or shelter before being transferred to the dealer; and
 - D. The date the dog or cat was transferred to the dealer.
- [3. Any licensee who obtains or acquires a dog or cat from a pound or shelter, including a pound or shelter s/he operates, shall hold the dog or cat for a period of at least ten (10) full days, not including the day of acquisition, excluding time in transit, after acquiring the animal.]

AUTHORITY: sections 273.344 and 273.346, RSMo [1994] 2000. Original rule filed Jan. 13, 1994, effective Aug. 28, 1994. Amended: Filed Oct. 24, 1994, effective May 28, 1995. Amended: Filed Nov. 30, 1995, effective July 30, 1996. Amended: Filed May 15, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Jerry Eber, DVM, Veterinarian II, Missouri Department of Agriculture, Division of Animal Health, PO Box 630, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 2—DEPARTMENT OF AGRICULTURE Division 30—Animal Health Chapter 9—Animal Care Facilities

PROPOSED AMENDMENT

2 CSR 30-9.030 Animal Care Facilities Minimum Standards of Operation and Transportation. The director is deleting part (1)(F)3.A.(IV).

PURPOSE: This proposed amendment allows Missouri's regulations to be compatible with current USDA regulations.

- (1) Facilities and Operating Standards.
- (F) Primary Enclosures. Primary enclosures for animals must meet the following minimum requirements:
 - 1. General requirements.
- A. Primary enclosures must be designed and constructed of suitable materials so that they are structurally sound. The primary enclosure must be kept in good repair.
- B. Primary enclosures must be constructed and maintained so that they—
- (I) Have no sharp points or edges that could injure the animals;
 - (II) Protect the animals from injury;
 - (III) Contain the animals securely;
 - (IV) Keep other animals from entering the enclosure;
 - (V) Enable the animals to remain dry and clean;
- (VI) Provide shelter and protection from extreme temperatures and weather conditions that may be uncomfortable or hazardous to the animals;
- (VII) Provide sufficient shade to shelter all the animals housed in the primary enclosure at one time;
- (VIII) Provide all the animals with easy and convenient access to clean food and water:
- (IX) Enable all surfaces in contact with the animals to be readily cleaned and sanitized in accordance with this rule, or be replaceable when worn or soiled;
- (X) Have floors that are constructed in a manner that protects the animals' feet and legs from injury and that, if mesh or slatted construction, it must be constructed of materials strong enough to prevent sagging and with a mesh small enough that will not allow the animals' feet to pass through any openings in the floor. If the floor of the primary enclosure is constructed of wire, a solid resting surface(s) that, in the aggregate, is large enough to hold all the occupants of the primary enclosure at the same time comfortably must be provided; and

- (XI) Provide sufficient space to allow each animal to turn about freely, to stand, sit and lie in a comfortable, normal position and to walk in a normal manner;
 - 2. Additional requirements for cats.
- A. Space. Each cat, including weaned kittens, that is housed in any primary enclosure must be provided minimum vertical space and floor space as follows:
- (I) Each primary enclosure housing cats must be at least twenty-four inches (24") high or sixty point ninety-six centimeters (60.96 cm). Temporary housing such as queening cages may be reduced to a height of eighteen inches (18") or forty-five point seventy-two centimeters (45.72 cm) to reduce injury to kittens;
- (II) Cats up to and including eight point eight (8.8) pounds or four (4) kilograms, must be provided with at least three point zero (3.0) square feet or zero point twenty-eight (0.28) square meters;
- (III) Cats over eight point eight (8.8) pounds or four (4) kilograms must be provided with at least four point zero (4.0) square feet or zero point thirty-seven (0.37) square meters;
- (IV) Each queen with nursing kittens must be provided with an additional amount of floor space, based on her breed and behavioral characteristics, and in accordance with generally accepted husbandry practices. If the additional amount of floor space for each nursing kitten is equivalent to less than five percent (5%) of the minimum requirement for the queen, the housing must be approved by the state veterinarian; and
- (V) The minimum floor space required by this section is exclusive of any food or water pans. The litter pan may be considered part of the floor space if properly cleaned and sanitized.
- B. Compatibility. All cats housed in the same primary enclosure must be compatible, as determined by observation. Not more than twelve (12) adult nonconditioned cats may be housed in the same primary enclosure. Queens in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, queens with litters may not be housed in the same primary enclosure with other adult cats, and kittens under four (4) months of age may not be housed in the same primary enclosure with adult cats, other than the dam or foster dam. Cats with a vicious or aggressive disposition must be housed separately.
- C. Litter. In all primary enclosures, a receptacle containing sufficient clean litter must be provided to contain excreta and body wastes
- D. Resting surfaces. Each primary enclosure housing cats must contain a resting surface(s) that, in the aggregate, are large enough to hold all the occupants of the primary enclosure at the same time comfortably. The resting surfaces must be elevated, impervious to moisture and be able to be easily cleaned and sanitized or easily replaced when soiled or worn.
- (I) Low resting surfaces that do not allow the space under them to be comfortably occupied by the animal will be counted as part of the floor space. Floor space under low resting surfaces shall not be counted as floor space to meet the minimum space requirements.
- (II) Elevated resting surfaces will not be required for shortterm housing facilities such as boarding kennels, commercial kennels, contract kennels, pet shops, pounds or dog pounds, however, elevated resting surfaces may be properly installed to increase floor space to that required in this rule; and
 - 3. Additional requirements for dogs.

A. Space.

(I) Each dog housed in a primary enclosure (including weaned puppies) must be provided a minimum amount of floor space, calculated as follows: Find the mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus six inches (6"); then divide the product by one hundred forty-four (144). The calculation is: (length of dog in inches plus six (6)) times (length of dog in inches plus six (6)) equals required floor space in square inches. Required floor space in inch-

es divided by one hundred forty-four (144) equals required floor space in square feet.

- (II) Each bitch with nursing puppies must be provided with an additional amount of floor space, based on her breed and behavioral characteristics, and in accordance with generally accepted husbandry practices as determined by the attending veterinarian. If the additional amount of floor space for each nursing puppy is less than five percent (5%) of the minimum requirement for the bitch, this housing must be approved by the state veterinarian.
- (III) The interior height of a primary enclosure must be at least six inches (6") higher than the head of the tallest dog in the enclosure when it is in a normal standing position.

[(IV) Dogs on tethers.

- (a) Dogs may be kept on tethers only in outside housing facilities that meet the requirements of this rule, and then only when the tether meets the requirements of this paragraph. The tether must be attached to the front of the dog's shelter structure or to a post in front of the shelter structure and must be at least three (3) times the length of the dog, as measured from the tip of its nose to the base of its tail. The tether must allow the dog convenient access to the shelter structure and to food and water containers. The tether must be of the type and strength commonly used for the size dog involved and must be attached to the dog by a well-fitted collar that will not cause trauma or injury to the dog. Collars made of materials such as wire, flat chains, chains with sharp edges, or chains with rusty or nonuniform links are prohibited. The tether must be attached so that the dog cannot become entangled with other objects or come into physical contact with other dogs in the outside housing facility, and so the dog can roam to the full range of the teth-
- (b) Dog housing areas where dogs are on tethers must be enclosed by a perimeter fence that is of sufficient height to keep unwanted animals out. Fences less than six feet (6') high must be approved by the state veterinarian. The fence must be constructed so that it protects the dogs by preventing animals the size of dogs, skunks and raccoons from going through it or under it and having contact with the dogs inside.]
- B. Compatibility. All dogs housed in the same primary enclosure must be compatible, as determined by observation. Not more than twelve (12) adult nonconditioned dogs may be housed in the same primary enclosure. Bitches in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, bitches with litters may not be housed in the same primary enclosure with other adult dogs, and puppies under four (4) months of age may not be housed in the same primary enclosure with adult dogs, other than their dam or foster dam. Dogs with a vicious or aggressive disposition must be housed separately.

AUTHORITY: sections 273.344 and 273.346, RSMo [1994] 2000. Original rule filed Jan. 13, 1994, effective Aug. 28, 1994. Amended: Filed Nov. 30, 1995, effective July 30, 1996. Amended: Filed May 15, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Jerry Eber, DVM, Veterinarian II, Missouri Department of Agriculture, Division of Animal Health, PO Box 630, Jefferson City, MO 65102.

To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 4—Wildlife Code: General Provisions

PROPOSED AMENDMENT

3 CSR 10-4.111 Endangered Species. The commission proposes to amend section (3).

PURPOSE: This amendment adds the eastern and Ozark hellbender to the state endangered list; adds the new subsection of Amphibians; and reorders the subsections taxonomically, beginning with mammals and ending with plants.

- [(3) For the purpose of this rule, endangered species of wildlife and plants shall include the following native species designated as endangered in Missouri:
- (A) Birds: Northern Harrier, Interior Least Tern, Barn-Owl, Swainson's Warbler, Snowy Egret, King Rail, Bachman's Sparrow, Bald Eagle, Peregrine Falcon, American Bittern, Greater Prairie-Chicken.
- (B) Mammals: Gray Bat, Ozark Big-eared Bat, Indiana Bat, Mountain Lion, Black-tailed Jackrabbit, Spotted Skunk.
- (C) Fishes: Lake Sturgeon, Pallid Sturgeon, Taillight Shiner, Neosho Madtom, Spring Cavefish, Harlequin Darter, Goldstripe Darter, Cypress Minnow, Central Mudminnow, Crystal Darter, Swamp Darter, Ozark Cavefish, Niangua Darter, Sabine Shiner, Mountain Madtom, Redfin Darter, Longnose Darter, Flathead Chub, Topeka Shiner.
- (D) Reptiles: Western Chicken Turtle, Blanding's Turtle, Illinois Mud Turtle, Yellow Mud Turtle, Western Fox Snake, Mississippi Green Water Snake, Massasauga.
- (E) Mussels: Curtis Pearlymussel, Higgins' Eye, Pink Mucket, Fat Pocketbook, Ebonyshell, Elephant Ear, Winged Mapleleaf, Sheepnose, Snuffbox, Scaleshell.
- (F) Plants: Small Whorled Pogonia, Mead's Milkweed, Decurrent False Aster, Missouri Bladderpod, Geocarpon, Running Buffalo Clover, Pondberry, Eastern Prairie Fringed Orchid, Western Prairie Fringed Orchid, Virginia Sneezeweed.
- (G) Invertebrates: American Burying Beetle, Hine's Emerald Dragonfly, Tumbling Creek Cave Snail.]
- (3) For the purpose of this rule, endangered species of wildlife and plants shall include the following native species designated as endangered in Missouri:
- (A) Mammals: gray bat, Ozark big-eared bat, Indiana bat, mountain lion, black-tailed jackrabbit, spotted skunk.
- (B) Birds: northern harrier, interior least tern, barn-owl, Swainson's warbler, snowy egret, king rail, Bachman's sparrow, bald eagle, peregrine falcon, American bittern, greater prairie-chicken.
- (C) Reptiles: western chicken turtle, Blanding's turtle, Illinois mud turtle, yellow mud turtle, western fox snake, Mississippi green water snake, massasauga.
 - (D) Amphibians: eastern hellbender, Ozark hellbender.
- (E) Fishes: lake sturgeon, pallid sturgeon, taillight shiner, Neosho madtom, spring cavefish, harlequin darter, goldstripe darter, cypress minnow, central mudminnow, crystal darter, swamp darter, Ozark cavefish, Niangua darter, Sabine shiner, mountain madtom, redfin darter, longnose darter, flathead chub, Topeka shiner.

- (F) Mussels: Curtis pearlymussel, Higgins' eye, pink mucket, fat pocketbook, ebonyshell, elephant ear, winged mapleleaf, sheepnose, snuffbox, scaleshell.
- (G) Other Invertebrates: American burying beetle, Hine's emerald dragonfly, Tumbling Creek cavesnail.
- (H) Plants: small whorled pogonia, Mead's milkweed, decurrent false aster, Missouri bladderpod, geocarpon, running buffalo clover, pondberry, eastern prairie fringed orchid, western prairie fringed orchid, Virginia sneezeweed.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section 252.240, RSMo 2000. Original rule filed Aug. 15, 1973, effective Dec. 31, 1973. For intervening history, please consult the Code of State Regulations. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 7—Wildlife Code: Hunting: Seasons, Methods, Limits

PROPOSED AMENDMENT

3 CSR 10-7.410 Hunting Methods. The commission proposes to amend subsection (1)(H).

PURPOSE: This amendment provides clarification of the portions of deer seasons in which hunting restrictions apply for hunting other wildlife.

- (1) Wildlife may be hunted and taken only in accordance with the following:
- (H) Special Firearms Provision. During the November portion and [January] the antlerless-only portion[s] of the firearms deer season in deer management units open to deer hunting, other wildlife and feral hogs (any hog, including Russian and European wild boar, that is not conspicuously identified by ear tags or other forms of identification and is roaming freely upon public or private lands without the landowner's permission) may be hunted only with a shotgun and shot not larger than No. 4, except that this provision does not apply to waterfowl hunters, trappers or to a landowner on his/her land or to a lessee on the land on which s/he resides.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed July 22, 1974, effective Dec. 31, 1974. For intervening history, please consult the Code of State Regulations. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 7—Wildlife Code: Hunting: Seasons, Methods,
Limits

PROPOSED AMENDMENT

3 CSR 10-7.455 Turkeys: Seasons, Methods, Limits. The commission proposes to add section (8).

PURPOSE: This amendment supports section 270.400, RSMo to allow feral hog hunting during the firearms turkey seasons only by methods and permit requirements allowed during those hunting seasons.

(8) In accordance with section 270.400, RSMo feral hogs (any hog, including Russian and European wild boar, that is not conspicuously identified by ear tags or other forms of identification and is roaming freely upon public or private lands without the landowner's permission) may be taken in any number during the spring firearms turkey season and youth spring season only by the holder of a valid, unused turkey hunting permit; and only by methods and times prescribed for taking turkeys. During the fall firearms turkey season, feral hogs may be taken only by the holder of a valid, unused turkey hunting permit or a small game hunting permit; and only by methods prescribed in Chapter 7 for taking wildlife, and without the use of bait. Other restrictions may apply on public lands. Resident landowners or lessees as defined in this Code may take feral hogs on their own property at any time, by any method and without permit.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed Dec. 15, 1975, effective Dec. 31, 1975. For intervening history, please consult the Code of State Regulations. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 9—Wildlife Code: Confined Wildlife: Privileges,
Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.110 General Prohibitions; Applications. The commission proposes to amend section (1).

PURPOSE: This amendment removes hellbender from the list of species allowed to be taken and possessed by residents of Missouri.

(1) A maximum of (5) specimens of any native wildlife not listed in 3 CSR 10-4.110(4) or 3 CSR 10-9.240, except endangered species, bats, [hellbenders] and alligator snapping turtles, may be taken and possessed alive by a resident of Missouri without permit, but these animals shall not be bought or sold. Bones, skins, shells and other parts of such wildlife may be possessed for personal use without permit, but these wildlife parts in any form shall not be bought or sold.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule was previously filed as 3 CSR 10-4.110(5), (6) and (10). Original rule filed June 26, 1975, effective July 7, 1975. For intervening history, please consult the Code of State Regulations. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 11—Wildlife Code: Special Regulations for
Department Areas

PROPOSED AMENDMENT

3 CSR 10-11.160 Use of Boats and Motors. The commission proposes to amend subsection (1)(A).

PURPOSE: This amendment establishes outboard motor use regulations that are consistent with current U.S. Fish & Wildlife Service regulations on areas managed under agreement with the Department of Conservation.

- (1) Boats, including sailboats, may be used on lakes and ponds designated as open to boats, except as further restricted in this chapter. Boats may not be left unattended overnight. Houseboats, and personal watercraft as defined in section 306.010, RSMo, are prohibited. Registration and a fee are required for rental of department-owned boats. Fees must be paid prior to use.
- (A) Except as provided below, only electric motors are permitted on lakes and ponds of less than seventy (70) acres. Electric motors and outboard motors are permitted on lakes of seventy (70) or more acres and on certain areas in conjunction with waterfowl hunting, except as otherwise provided in paragraph (1)(A)3. of this rule. Outboard motors in excess of ten (10) horsepower must be operated at slow, no-wake speed, except as otherwise provided in paragraph (1)(A)4. of this rule.
- 1. On August A. Busch Memorial Conservation Area and James A. Reed Memorial Wildlife Area, only department-owned boats may be used and only electric motors are permitted.
- 2. On Hunnewell Lake Conservation Area, only departmentowned boats may be used.
- 3. On Robert G. DeLaney Lake Conservation Area, only electric motors are permitted.

- 4. On Thomas Hill Reservoir, boating is prohibited on the main arm of the lake above Highway T from October 15 through January 15. No other restrictions in this section apply to this area.
- 5. All boating is prohibited from November 15 through February 15 on the Theodosia Arm of Bull Shoals Lake described as: All of Section 13, and south half of Section 12, T22N, R16W; all of Section 17, south half of Sections 7 and 8, and that part of Sections 19 and 20 north of Highway 160 bridge, all in T22N, R15W. No other restrictions in this section apply to this area.
 - 6. On Bellefontaine Conservation Area, boats are prohibited.
- 7. Outboard motors of any size may be used on Overton Bottoms Conservation Area, but must be operated at slow, nowake speed.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.115. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed Oct. 1, 2001, effective Oct. 15, 2001. Amended: Filed May 9, 2002, effective March 1, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 11—Wildlife Code: Special Regulations for Department Areas

PROPOSED AMENDMENT

3 CSR 10-11.180 Hunting, General Provisions and Seasons. The commission proposes to amend sections (4), (6) and (7) of this rule.

PURPOSE: This amendment provides additional hunting opportunity on Truman Lake Management Land adjacent to the Clinton office; and, liberalizes firearm provisions on Drury-Mincy Conservation Area and restricts use of single projectile firearms on Columbia Bottom Conservation Area.

(4) Hunting is prohibited on the following department areas: [(FFFFF) West Central Regional Office] [(GGGGG)] (FFFFF) White Alloe Creek Wildcat Conservation Area

[(HHHHHH)] (GGGGG) Wildcat Glade Natural Area [(IIIIII)] (HHHHH) Walter Woods Conservation Area [(JJJJJJ)] (IIIII) Mark Youngdahl Urban Conservation Area

- (6) Firearms firing single projectiles are prohibited, except during managed deer hunts, and except furbearers treed with the aid of dogs may be taken with a twenty-two (.22) caliber firearm on the following department areas:
- (D) Truman Reservoir Management Lands (Clinton Wildlife Management Area)
- (7) Firearms firing single projectiles are prohibited, except during managed deer hunts on the following department areas:

[(B) Drury-Mincy Conservation Area]

(B) Columbia Bottom Conservation Area

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.115. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed May 9, 2002, effective Oct. 30, 2002. Amended: Filed July 31, 2002, effective Dec. 30, 2002. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 11—Wildlife Code: Special Regulations for Department Areas

PROPOSED AMENDMENT

3 CSR 10-11.182 Deer Hunting. The commission proposes to delete subsection (2)(RR), reletter the remaining subsections of (2), and amend subsection (4)(L).

PURPOSE: This amendment removes Hi Lonesome Prairie Conservation Area from the incorrect deer regulation listing, and corrects the area name.

(2) Deer may be hunted, under statewide seasons and limits, only by archery methods on the following department areas:

[(RR) Hi Lonesome Prairie Conservation Area]
[(SS)] (RR) Hinkson Woods Conservation Area
[(TT)] (SS) Hite Prairie Conservation Area
[(UU)] (TT) Hornersville Swamp Conservation Area
[(VV)] (UU) Horse Creek Prairie Conservation Area
[(WW)] (VV) Howell Island Conservation Area
[(XX)] (WW) Hyer Woods Conservation Area
[(YY)] (XX) Indigo Prairie Conservation Area
[(ZZ)] (YY) Jamesport Community Lake
[(AAA)] (ZZ) Anthony and Beatrice Kendzora Conservation Area
[(BBB)] (AAA) Kessler Memorial Wildlife Area
[(CCC)] (BBB) Wilford V. and Anna C. Kneib Memorial Conservation Area

[(DDD)] (CCC) Lake Girardeau Conservation Area
[(EEE)] (DDD) B. K. Leach Memorial Conservation Area
[(FFF)] (EEE) Little Bean Marsh Conservation Area
[(GGG)] (FFF) Little Dixie Lake Conservation Area
[(HHH)] (GGG) Little Prairie Conservation Area
[(IIII)] (HHH) Little River Conservation Area
[(JJJ)] (III) Caroline Sheridan Logan Memorial Wildlife Area

[(KKK)] (JJJ) Lon Sanders Canyon Conservation Area

[(LLL)] (KKK) Lone Jack Lake Conservation Area

[(MMM)] (LLL) Lost Valley Fish Hatchery

[(NNN)] (MMM) Alice Ahart Mansfield Conservation Area

[(OOO)] (NNN) Merrill Horse Access

[(PPP)] (OOO) Mockingbird Hill Access

[(QQQ)] (PPP) Monegaw Prairie Conservation Area

[(RRR)] (QQQ) Mo-No-I Prairie Conservation Area

[(SSS)] (RRR) Mon-Shon Prairie Conservation Area

[(TTT)] (SSS) Montrose Conservation Area [(UUU)] (TTT) Mound View Access [(VVV)] (UUU) Nodaway Valley Conservation Area [(WWW)] (VVV) Old Town Access [(XXX)] (WWW) Pacific Palisades Conservation Area [(YYY)] (XXX) Guy B. Park Conservation Area [(ZZZ)] (YYY) Parma Woods Range and Training Center (north [(AAAA)] (ZZZ) Pilot Knob Conservation Area [(BBBB)] (AAAA) Platte Falls Conservation Area [(CCCC)] (BBBB) Prairie Slough Conservation Area [(DDDD)] (CCCC) J. Thad Ray Memorial Wildlife Area [(EEEE)] (DDDD) Redwing Prairie Conservation Area [(FFFF)] (EEEE) Reform Conservation Area [(GGGG)] (FFFF) Rocky Barrens Conservation Area [(HHHHH)] (GGGG) Rocky Mount Towersite [(////)] (HHHH) Schell-Osage Conservation Area [(JJJJ)] (IIII) Ted Shanks Conservation Area [(KKKK)] (JJJJ) Sky Prairie Conservation Area [(LLLL)] (KKKK) Dr. O.E. and Eloise Sloan Conservation Area [(MMMM)] (LLLL) Sni-A-Bar Conservation Area [(NNNN)] (MMMM) Sterling Price Community Lake [(OOOO)] (NNNN) Sunbridge Hills Conservation Area [(PPPP)] (OOOO) Swift Ditch Access [(QQQQ)] (PPPP) Ten Mile Pond Conservation Area [(RRRR)] (QQQQ) Tipton Ford Access [(SSSS)] (RRRR) Treaty Line Prairie Conservation Area [(TTTT)] (SSSS) Upper Mississippi Conservation Area (Bay Island Unit) [(UUUU)] (TTTT) Upper Mississippi Conservation Area (Dresser Island Unit)

[(VVVV)] (UUUU) Valley View Glades Natural Area [(WWWW)] (VVVV) Archie and Gracie Vanderhoef Memorial

[(XXXX)] (WWWW) Victoria Glades Conservation Area /(YYYY)/ (XXXX) Vonaventure Memorial Forest and Wildlife

[(ZZZZ)] (YYYY) Warbler Woods Conservation Area [(AAAAA)] (ZZZZ) Henry Jackson Waters and C. B. Moss Memorial Wildlife Area

[(BBBBB)] (AAAAA) George O. White State Forest Nursery [(CCCCC)] (BBBBB) Wolf Bayou Conservation Area [(DDDDD)] (CCCCC) Yellow Creek Conservation Area [(EEEEE)] (DDDDD) Young Conservation Area

- (4) Deer may be hunted, under statewide seasons and limits, only by archery and muzzleloader methods on the department areas listed below:
 - (L) Hi Lonesome Prairie Conservation Area

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.115. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed Aug. 30, 2001, effective Jan. 30, 2002. Amended: Filed May 9, 2002, effective Oct. 30, 2002. Amended: Filed June 5, 2002, effective Nov. 30, 2002. Amended: Filed July 31, 2002, effective March 1, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180,

Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION **Division 10—Conservation Commission** Chapter 11—Wildlife Code: Special Regulations for **Department Areas**

PROPOSED AMENDMENT

3 CSR 10-11.186 Waterfowl Hunting. The commission proposes to amend section (2) of this rule.

PURPOSE: This amendment opens Hunnewell Conservation Area to waterfowl hunting opportunity.

(2) Waterfowl hunting is prohibited on the following department areas:

[(B) Hunnewell Lake Conservation Area]

[(C)] (B) Lake Girardeau Conservation Area

[(D)] (C) Lake Paho Conservation Area

[(E)] (D) Lone Jack Lake Conservation Area

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.115. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed May 9, 2002, effective March 1, 2003. Amended: Filed July 31, 2002, effective June 30, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION **Division 10—Conservation Commission** Chapter 11—Wildlife Code: Special Regulations for **Department Areas**

PROPOSED AMENDMENT

3 CSR 10-11.205 Fishing, Methods and Hours. The commission proposes to amend subsection (1)(B).

PURPOSE: This amendment legalizes the taking of rough fish by gig, longbow or crossbow in the wetland pools and other impounded waters on Columbia Bottom Conservation Area.

- (1) On lakes and ponds, fish may be taken only with pole and line and not more than three (3) poles may be used by one (1) person at any time, except as otherwise provided in this chapter.
- (B) Carp, buffalo, suckers and gar may be taken by gig, longbow or crossbow during statewide seasons on the following department areas or individually named lakes:
 - 1. Atlanta Conservation Area
 - 2. Bismarck Conservation Area
 - 3. Blackjack Access

- 4. Bob Brown Conservation Area
- 5. Columbia Bottom Conservation Area
- [5.] 6. Cooley Lake Conservation Area
- [6.] 7. Deer Ridge Conservation Area
- [7.] 8. Deroin Bend Conservation Area
- [8.] 9. Duck Creek Conservation Area
- [9.] 10. Eagle Bluffs Conservation Area
- [10.] 11. Connor O. Fewel Conservation Area
- [11.] 12. Fountain Grove Conservation Area
- [12.] 13. Four Rivers Conservation Area
- [13.] 14. Franklin Island Conservation Area
- [14.] 15. Grand Pass Conservation Area
- [15.] 16. Hunnewell Lake Conservation Area
- [16.] 17. King Lake Conservation Area
- [17.] 18. Kings Prairie Access
- [18.] 19. Lake Paho Conservation Area
- [19.] 20. Lamine River Conservation Area
- [20.] 21. B.K. Leach Memorial Conservation Area
- [21.] 22. Limpp Community Lake
- [22.] 23. Little Compton Lake Conservation Area
- [23.] 24. Locust Creek Conservation Area
- [24.] 25. Manito Lake Conservation Area
- [25.] 26. Marais Temps Clair Conservation Area
- [26.] 27. Nodaway Valley Conservation Area
- [27.] 28. Otter Lake (Otter Slough Conservation Area)
- [28.] 29. Peabody Conservation Area
- [29.] 30. Ralph and Martha Perry Memorial Conservation Area
- [30.] 31. Haysler A. Poague Conservation Area
- [31.] 32. Pony Express Lake Conservation Area
- [32.] 33. Rebel's Cove Conservation Area
- [33.] 34. Schell-Osage Conservation Area
- [34.] 35. Henry Sever Lake Conservation Area
- [35.] 36. Settle's Ford Conservation Area
- [36.] 37. Ted Shanks Conservation Area
- [37.] 38. H. F. Thurnau Conservation Area
- [38.] 39. Truman Reservoir Management Lands
- [39.] 40. Worth County Community Lake
- [40.] 41. Worthwine Island Conservation Area

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.115. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed May 9, 2002, effective March 1, 2003. Amended: Filed July 31, 2002, effective June 30, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 12—Wildlife Code: Special Regulations for Areas Owned by Other Entities

PROPOSED AMENDMENT

3 CSR 10-12.110 Use of Boats and Motors. The commission proposes to amend sections (5) and (8).

PURPOSE: This amendment changes restrictions on outboard boat motor use at Odessa City Lake.

- (5) Outboard motors not in excess of ten (10) horsepower may be used on the following areas:
 - [(F) Odessa City Lake]
 - [(G)] (F) Springfield City Utilities (Lake Springfield)
 - [(H)] (G) Unionville (Lake Mahoney)
 - [(//)] (H) Wakonda State Park (Agate Lake and Wakonda Lake)
 - [(J)] (I) Watkins Mill State Park Lake
- (8) Outboard motors of any size may be used on Concordia (Edwin A. Pape Lake) and Odessa City Lake, but must be operated at slow, no-wake speed.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.116. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed Aug. 30, 2001, effective Jan. 30, 2002. Amended: Filed May 9, 2002, effective March 1, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 12—Wildlife Code: Special Regulations for Areas Owned by Other Entities

PROPOSED AMENDMENT

3 CSR 10-12.135 Fishing, Methods. The commission proposes to amend sections (7) and (8).

PURPOSE: This amendment establishes fishing methods for a winter trout fishery at the City of Jackson's Rotary Lake.

- (7) Only flies, artificial lures and soft plastic baits (unscented) may be used from November 1 through January 31 on the following lakes[;]:
 - (A) Jackson (Rotary Lake)
 - [(A)] (B) Kirkwood (Walker Lake)
 - [(B)] (C) Overland (Wild Acres Park Lake)
 - [(C)] (D) St. Louis City (Jefferson Lake)
 - [(D)] (E) St. Louis County (Tilles Park Lake)
- (8) From November 1 through January 31, not more than one (1) pole and line may be used by one (1) person at any time and the use of natural or scented baits as chum is prohibited on the following lakes:
 - (C) Jackson (Rotary Lake)
 - [(C)] (D) Kirkwood (Walker Lake)
 - [(D)] (E) Overland (Wild Acres Park Lake)
- [[E]] (F) St. Louis City (Boathouse Lake, Jefferson Lake, O'Fallon Park Lake)
- [(F)] (G) St. Louis County (Suson Park Lakes No. 1, 2, 3, Tilles Park Lake)

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.116. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed Aug. 30, 2001, effective Jan. 30, 2002. Amended: Filed May 9, 2002, effective Oct. 30, 2002. Amended: Filed July 31, 2002, effective March 1, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 12—Wildlife Code: Special Regulations for
Areas Owned by Other Entities

PROPOSED AMENDMENT

3 CSR 10-12.140 Fishing, Daily and Possession Limits. The commission proposes to amend sections (13) and (14).

PURPOSE: This amendment establishes a winter catch-and-release fishing season for trout at the City of Jackson's Rotary Lake; and, corrects a location reference.

- (13) Trout must be returned to the water unharmed immediately after being caught from November 1 through January 31 on [Kirkwood (Walker Lake), Overland (Wild Acres Park Lake), St. Louis City (Jefferson Lake) and St. Louis County (Tilles Park Lake)] the lakes listed below. Trout may not be possessed on these waters during this season.
 - (A) Jackson (Rotary Lake)
 - (B) Kirkwood (Walker Lake)
 - (C) Overland (Wild Acres Park Lake)
 - (D) St. Louis City (Jefferson Lake)
 - (E) St. Louis County (Tilles Park Lake)
- (14) No person shall continue to fish for any species after having five (5) trout in possession from November 1 through January 31 on the following lakes:
 - (D) St. Louis [City] County (Suson Park Lakes No. 1, 2, and 3)

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This rule previously filed as 3 CSR 10-4.116. Original rule filed April 30, 2001, effective Sept. 30, 2001. Amended: Filed Aug. 30, 2001, effective Jan. 30, 2002. Amended: Filed May 9, 2002, effective Oct. 30, 2002. Amended: Filed July 31, 2002, effective March 1, 2003. Amended: Filed May 9, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

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NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with John W.

Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION

Division 60—Vocational and Adult Education Chapter 900—Veterans' Education

PROPOSED AMENDMENT

5 CSR 60-900.050 Standards for the Approval of Courses for the Education of Persons Under Veterans' Education and Vocational Rehabilitation. The State Board of Education is proposing to amend subsections (1)(A), (1)(J), (3)(M), (4)(C) and (4)(G).

PURPOSE: This amendment clarifies the procedures for determining the amounts paid by the Division of Vocational Rehabilitation for training.

- (1) All references to the State Board of Education (the board) in this rule may be construed to include the Department of Elementary and Secondary Education (DESE) and the appropriate program sections. The provisions of this section apply to accredited courses and nonaccredited courses.
- (A) A course shall not be approved unless the institution has operated that course successfully for a period of twenty-four (24) calendar months for veterans' education courses or six (6) calendar months or for one (1) graduating class for vocational rehabilitation courses. Successful operation shall mean an operation which is sound educationally and financially. The following are exceptions:
- 1. Any course to be pursued in a public or other tax-supported educational institution;
- 2. Any course which is offered for veterans' education or vocational rehabilitation by a non-college (NCD) institution and/or a non-accredited institution of higher learning (IHL) where at least one (1) course is already approved;
- 3. Any course which has been offered by an educational institution for a period of more than two (2) years or six (6) calendar months, whichever is appropriate, notwithstanding the institution has moved to another location within the same general locality or has made a complete move with substantially the same faculty, curricula and students, without change in ownership;
- 4. Any course which is offered by an educational institution of college level and which is recognized for credit toward a standard college degree; or
- 5. Any course for vocational rehabilitation when a needed course is not available at any other institution offering approved courses within a *[fifty-five (55)]* forty-five (45)-mile commuting distance as approved by DESE.
- (J) The charges for tuition, fees and other charges for the course or program of education shall be reasonable, based on the services to be rendered, the books, supplies and equipment to be furnished and the operating costs of the institution and may be reimbursed pursuant to the rules promulgated by the board for vocational rehabilitation courses.
- (3) The provisions of this section apply to courses which cannot be considered as accredited courses pursuant to this rule.
- (M) The charges for tuition, fees and other charges for the course or program of education shall be reasonable, based on the services to be rendered, the books, supplies and equipment to be furnished and the operating costs of the institutions. These charges may be reimbursed pursuant to the rules promulgated by the board for vocational rehabilitation courses. The following referral policy applies only to eligible persons receiving veterans benefits:

- 1. The institution shall establish and maintain a policy for the refund of the unused portion of tuition, fees and other charges in the event an eligible person fails to enter the course or withdraws or is discontinued at any time prior to completion and the policy shall provide that the amount charged to the eligible person for tuition, fees and other charges for a portion of the course does not exceed the approximate *pro rata* portion of the total charges for tuition, fees and other charges that the length of the completed portion of the course bears to its total length.
- (4) The provisions of this section apply to charges and reimbursements for accredited and nonaccredited courses. For the purpose of administering this rule, an individual referral is a student referred by a sponsoring agency for skill training or training-related service for which DESE has contracted to reimburse a public, not-for-profit or for-profit institution **pursuant to the rules promulgated by the board for vocational rehabilitation**. The cost of training for individual referrals with the Division of Vocational Rehabilitation shall be reimbursed in the following way:
- (C) Tuition payments shall be made on the basis of the school's instructional periods, (that is, quarters, terms or semesters) and will be reimbursed pursuant to the rules promulgated by the board for vocational rehabilitation. However, the following guidelines shall apply:
- 1. Any instructional period that is at least twenty (20) weeks but no more than thirty-nine (39) weeks, will be treated as having a minimum of two (2) equal instructional periods;
- 2. Any instruction period that is at least forty (40) weeks but no more than fifty-nine (59) weeks, will be treated as three (3) equal instructional periods. Programs of instruction in licensed practical nursing, surgical technology, respiratory therapy, dental technology, emergency medical technician–paramedic, radiology and massage therapy are excluded;
- 3. Courses with instructional periods that are at least sixty (60) weeks or more will be divided into additional segments of twenty (20) weeks; and/or
- 4. The total instructional program for licensed practical nursing, surgical technology, respiratory therapy, dental technology, emergency medical technician-paramedic, radiology and/or massage therapy will be treated as one (1) instructional period;
- (G) Institutions shall submit reimbursement request for tuition payments of individual referrals for each instructional period pursuant to the rules promulgated by the board for vocational rehabilitation; and

AUTHORITY: sections 161.092, RSMo Supp. 2002 and 161.172, 178.430, 178.530, 178.590 and 178.610, RSMo 2000. Original rule filed July 7, 2000, effective Feb. 28, 2001. Amended: Filed Sept. 24, 2002, effective April 30, 2003. Amended: Filed May 2, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Department of Elementary and Secondary Education, Attention Mr. Ronald W. Vessell, Assistant Commissioner, Division of Vocational Rehabilitation, 3024 W. Truman Blvd., Jefferson City, MO 65109. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 9—DEPARTMENT OF MENTAL HEALTH Division 10—Director, Department of Mental Health Chapter 5—General Program Procedures

PROPOSED AMENDMENT

9 CSR 10-5.200 Report of Complaints of Abuse, Neglect and Misuse [of] Funds/Property. The department proposes to amend the Purpose and sections (1)–(3), (6), (7), (9), (11) and (14).

PURPOSE: This proposed amendment will narrow the definition of verbal abuse to specify abuse directed at a consumer; and make minor revisions to correct grammar, clarify confusing language, and increase language consistency with related department operating regulations and administrative rules.

PURPOSE: This rule prescribes procedures for reporting and investigating complaints of abuse, neglect and misuse [of] funds/property in a residential facility, day program or specialized service that is licensed, certified or funded by the Department of Mental Health (department) as required by sections 630.135, 630.168, 630.655 and 630.710, RSMo. The rule also sets forth due process procedures for persons who have been accused of abuse, neglect and misuse [of] funds/property.

- (1) The following words and terms, as used in this rule, mean:
- (A) Class I neglect, failure of an employee to provide reasonable *[and]* or necessary services to maintain the physical and mental health of any consumer when that failure presents either imminent danger to the health, safety or welfare of a consumer, or a substantial probability that death or physical injury would result;
- (D) Misuse [of] funds/property, the misappropriation or conversion of a consumer's funds or property by an employee for another person's benefit;
 - (E) Physical abuse-
- 1. [Purposefully] An employee purposefully beating, striking, wounding or injuring any consumer; or
- 2. In any manner whatsoever, an employee mistreating or maltreating a consumer in a brutal or inhumane manner. Physical abuse includes handling a consumer with any more force than is reasonable for a consumer's proper control, treatment or management;
- (F) Sexual abuse, any touching, directly or through clothing, of a consumer **by an employee** for sexual purpose or in a sexual manner. This includes but is not limited to:
 - 1. Kissing;
 - 2. Touching of the genitals, buttocks or breasts;
- 3. Causing a consumer to touch the employee for sexual purposes;
- 4. Promoting or observing for sexual purpose any activity or performance involving consumers including any play, motion picture, photography, dance, or other visual or written representation; or
- 5. Failing to intervene or attempt to stop or prevent inappropriate sexual activity or performance between consumers; and
- (G) Verbal abuse, **an employee** using profanity or speaking in a demeaning, nontherapeutic, undignified, threatening or derogatory manner *[in a consumer's presence]* to a consumer.
- (2) This section applies to any employee or consumer of any residential facility, day program or specialized service, as defined under section 630.005, RSMo. Facilities, programs and services that are operated by the department are regulated by the department's operating regulations and are not included in this definition.
- (A) Any such employee who has reasonable cause to believe that a consumer has been subjected to physical abuse, sexual abuse, misuse *[of]* funds/property, class I neglect, class II neglect or verbal abuse while under the care of a residential facility, day program or specialized service that is licensed, certified or funded by the department shall immediately make a verbal or written complaint.

- (3) The head of the facility, day program or specialized service that is licensed, certified or funded by the department shall immediately report to the local law enforcement official any alleged or suspected—
- (C) Abuse, neglect or misuse [of] funds/property which may result in a criminal charge.
- (6) Within ten (10) working days of receiving the final report from the board of inquiry, local investigator or central investigative unit, **if there is a preliminary determination of abuse, neglect or misuse funds/property,** the head of the supervising facility or department designee shall send to the alleged perpetrator a summary of the allegations and findings which are the basis for the alleged abuse/neglect/misuse [of] funds or property; the provider will be copied. The summary shall comply with the constraints regarding confidentiality contained in section 630.167, RSMo and shall be sent by regular and certified mail.
- (C) Within ten (10) working days of the meeting, or if no request for a meeting is received within ten (10) working days of the alleged perpetrator's receipt of the summary, the head of the supervising facility or department designee shall make a final determination as to whether abuse/neglect/misuse [of] funds or property took place. The perpetrator shall be notified of this decision by regular and certified mail; the provider will be copied.
- (D) The letter shall advise the perpetrator that they have ten (10) working days following receipt of the letter to contact the department's hearings administrator if they wish to appeal a finding of abuse, neglect or misuse [of] funds/property.
- (7) If an appeal is requested, the hearings administrator shall schedule the hearing to take place within thirty (30) working days of the request, but may delay the hearing for good cause shown. At the hearing, the head of the supervising facility or designee, or other department designee shall present evidence supporting its findings of abuse, neglect, misuse *[of]* funds/property, or all. The provider or perpetrator may submit comments or present evidence to show why the decision of the head of the supervising facility or department designee should be modified or overruled. The hearings administrator may obtain additional information from department employees as s/he deems necessary.
- (9) The opportunities described in sections (6), (7) and (8) of this rule regarding a meeting with the head of the supervising facility and an appeal before the department's hearings administrator apply also to providers and alleged perpetrators in an investigation of misuse *lof1* funds/property.
- (11) If the department substantiates that a person has perpetrated physical abuse, sexual abuse, class I neglect, or misuse [of] funds/property, the perpetrator shall not be employed by the department, nor be licensed, employed or provide services by contract or agreement at a residential facility, day program or specialized service that is licensed, certified or funded by the department. The perpetrator's name shall be placed on the department Disqualification Registry pursuant to section 630.170, RSMo.
- (14) No director, supervisor or employee of a residential facility, day program or specialized service shall evict, harass, dismiss or retaliate against a consumer or employee because he or she or any member of his or her family has made a report of any violation or suspected violation of consumer abuse, neglect or misuse [of] funds/property. Penalties for retaliation may be imposed up to and including cancellation of agency contracts and/or dismissal of such person.

AUTHORITY: sections 630.050, 630.135, 630.165, 630.167, 630.168, 630.655 and 630.705, RSMo 2000 and 630.170, RSMo Supp. 2001. Original rule filed Oct. 29, 1998, effective May 30,

1999. Emergency amendment filed March 29, 2002, effective May 2, 2002, terminated Oct 30, 2002. Amended: Filed March 29, 2002, effective Oct. 30, 2002. Amended: Filed May 5, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Rebecca Carson, Deputy Director, Office of Quality Management, Department of Mental Health, PO Box 687, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 10-Air Conservation Commission
Chapter 6-Air Quality Standards, Definitions, Sampling
and Reference Methods and Air Pollution Control
Regulations for the Entire State of Missouri

PROPOSED AMENDMENT

10 CSR 10-6.110 Submission of Emission Data, Emission Fees and Process Information. The commission proposes to amend subsection (1)(A), add new section (2), renumber original section (2) to new section (3) and amend it to include original sections (2) through (8), and add new sections (4) and (5). If the commission adopts this rule action, it will be submitted to the U.S. Environmental Protection Agency to replace the current rule in the Missouri State Implementation Plan. The evidence supporting the need for this proposed rulemaking is available for viewing at the Missouri Department of Natural Resources' Air Pollution Control Program at the address and phone number listed in the Notice of Public Hearing at the end of this rule.

PURPOSE: This amendment will establish emission fees for Missouri facilities as required annually and provide provisions for permits-by-rule. The evidence supporting the need for this proposed rulemaking, per section 536.016, RSMo, is section 643.079 of the Missouri state statutes.

(1) Applicability.

- (A) This rule applies to any installation that: **notifies and accepts a permit-by-rule under 10 CSR 10-6.062**, is required to obtain a permit under 10 CSR 10-6.060 or 10 CSR 10-6.065, is required to file an Emission Inventory Questionnaire (EIQ) as outlined in the Reporting Frequency table in [subsection (2)(E)] paragraph (3)(A)5. of this rule, or is required by the staff director to prove its potential emissions are below *de minimis* levels.
- (2) Definitions. Definitions of certain terms specified in this rule may be found in 10 CSR 10-6.020.
- (3) General Provisions.
- [(2)] (A) Record Keeping and Reporting Requirements.
- [(A)] 1. The owner or operator of an installation that is a source of any air contaminant shall collect, record and maintain, during each calendar year of operation—the time period and duration of emissions; the amounts of processed materials, fuels and solvents consumed; and the amounts of process materials, fuels and solvents stored in tanks and storage piles which emit any regulated air pollutant.

[(B)] 2. The owner or operator of an installation subject to [subsection (2)(A)] paragraph (3)(A)1. of this rule shall file with the director, on the frequency specified in [subsection (2)(E)] paragraph (3)(A)5. of this rule, reports containing the information specified in [subsection (2)(A)] paragraph (3)(A)1. of this rule. The reports shall specify the type and location of all sources of regulated air pollutants and the amount of each type of regulated air pollutant at each location; the size and height of all emission outlets, stacks and vents; the processes employed, including all fuel combustion and incineration; the type of air pollution control equipment used at the installation; the capture efficiency and control efficiency of the air pollution control equipment, where applicable; and ozone season information (Form 2.0Z) from sources located in nonattainment areas. Capture efficiency shall be applicable to emission points which are controlled by air pollution control devices and are not fully enclosed. Capture efficiency is not applicable to fugitive dust. The department encourages facilities to perform tests to determine capture efficiency. Industrial ventilation principles and engineering calculations may be used if testing is physically impossible or cost prohibitive. If testing or engineering calculation is not possible, then a default value of fifty percent (50%) capture efficiency may be used. Documentation verifying the capture efficiency shall be included with the EIQ. The owner or operator may submit a report containing information of a different nature provided the information submitted is adequate for the purposes of air quality planning and fee assessment and is approved by the director. Information submitted shall be reduced by the director to emission data as defined in 10 CSR 10-6.210(3)(B)2.

[(C)] 3. The reports required by [subsections (2)(B) and (2)(D)] paragraphs (3)(A)2. and 4. of this rule shall be completed on state supplied EIQ forms or in a form satisfactory to the director and shall be submitted to the director within ninety (90) days after the end of each reporting period. After the effective date of this rule,

any revision to the EIQ forms will be presented to the regulated community for a forty-five (45)-day comment period. The reporting periods for an installation, as determined by the reporting frequency specified in [subsection (2)[E]] paragraph (3)(A)5. of this rule, shall end on December 31 of each calendar year. Sources allowed to file reports once every five (5) years shall submit the EIQ on the same schedule as the operating permit renewal application. Each report shall contain the information required by [subsection (2)[B]] paragraph (3)(A)2. of this rule for each air contaminant source at the installation for the twelve (12)-month period immediately preceding the end of the reporting period, in addition to the information required under [subsection (2)[A]] paragraph (3)(A)1. of this rule to be collected, recorded and maintained during each year of operation of the installation.

[(D)] 4. For sources located in nonattainment areas, an emission statement is required if the actual emission of either nitrogen oxides (NO_x), volatile organic compounds (VOCs) or carbon monoxide (CO) are equal to or greater than ten (10) tons annually. Emissions of each pollutant shall be reported if a facility meets the ten (10) ton threshold for any of the three (3). Emissions statement reporting requirements shall be completed on state supplied EIQ forms and include the information required at [subsection (2)(B)] paragraph (3)(A)2. of this rule and ozone season information for VOC, NO_x and CO emissions and any other criteria pollutant requested by the director. After the effective date of this rule, any revision to the EIQ forms will be presented to the regulated community for a forty-five (45)-day comment period. Emission statements shall be submitted in accordance with the schedule in [subsection (2)(E)] paragraph (3)(A)5. of this rule.

[(E)] 5. The reports required by [subsections (2)(B) and (D)] paragraphs (3)(A)2. and 4. of this rule shall be filed on the following frequency:

Reporting Frequency

Installation Emission Inventory Questionnaire		nire	
Classification	Nonattainment Area	All Other	
1. Any installation required to obtain a Part 70, Intermediate or Basic State Operating Permit under 10 CSR 10-6.065.	Annually	Annually	
2. Any installation required to obtain a a construction permit under 10 CSR 10-6.060 or accepting a permit-by-rule under 10 CSR 10-6.062, but not an an operating permit.	Once every five years	Once every five years	
3. Any installation required to submit an EIQ by the director.	Within 45 days of request	Within 45 days of request	
4. Any installation whose actual emissions of VOC, ${\rm NO_x}$ or CO are equal to or greater than ten (10) tons/year.	Annually, an emission statement is required	Exempt, no emission statement required	

- [(F)] 6. All data collected and recorded in accordance with the provisions of this rule shall be retained by the owner or operator for not less than five (5) years after the end of the calendar year in which the data was collected and all these records shall be made available to the director upon his/her request.
- [(3)] (B) Specific Report Required. The director may require the owner or operator of an installation to submit compound specific emission rates when the information submitted pursuant to [subsection (2)(C)] paragraph (3)(A)3. of this rule does not provide sufficient information to determine whether specific compounds from the installation may cause a threat to public health or welfare.
- [(4)] (C) Public Availability of Emission Data and Process Information. Any information obtained pursuant to the rule(s) of the Missouri Air Conservation Commission that would not be entitled to confidential treatment under 10 CSR 10-6.210 shall be made available to any member of the public upon request.

[(5)] (D) Emission Fees.

- [(A)] 1. Any air contaminant source required to obtain a permit under sections 643.010-643.190, RSMo, except sources that produce charcoal from wood, shall pay an annual emission fee, regardless of their EIQ reporting frequency, of thirty-one dollars and no cents (\$31.00) per ton of regulated air pollutant emitted starting with calendar year [2002] 2003 in accordance with the conditions specified in [subsection (5)[B]] paragraph (3)(D)2. of this rule. For calendar year 2003, the fee shall be reduced by one dollar and no cents (\$1.00) per ton of regulated air pollutant emitted to reflect credit for fees collected for 2002 calendar year emissions for the Missouri Emission Inventory System project. Sources which are required to file reports once every five (5) years may use the information in their most recent EIQ to determine their annual emission fee.
 - [(B)] 2. General [R]requirements.
- [1.] A. The fee shall apply to the first four thousand (4,000) tons of each regulated air pollutant emitted. However, no air contaminant source shall be required to pay fees on total emissions of regulated air pollutants in excess of twelve thousand (12,000) tons in any calendar year. A permitted air contaminant source which emitted less than one (1) ton of all regulated pollutants shall pay a fee equal to the amount of one (1) ton.
- [2.] **B.** The fee shall be based on the information provided in the facility's EIQ.
- [3.] C. An air contaminant source which pays emissions fees to a holder of a certificate of authority issued pursuant to section 643.140, RSMo, may deduct those fees from the emission fee due under this section.
- [4.] **D.** The fee imposed under [subsection (5)(A)] paragraph (3)(D)1. of this rule shall not apply to carbon oxide emissions.
- [5.] E. The fees shall be due April 1 each year for emissions produced during the previous calendar year.
- [6.] **F.** The fees shall be payable to the Department of Natural Resources and shall be accompanied by the Emissions Inventory Questionnaire form or equivalent approved by the director.
- [7.] G. For the purpose of determining the amount of air contaminant emissions on which the fees are assessed, a facility shall be considered one (1) source under the definition of section 643.078.2, RSMo, except that a facility with multiple operating permits shall pay emission fees separately for air contaminants emitted under each individual permit.
- [(C)] 3. Fee [C]collection. The annual changes to this rule to establish emission fees for a specific year do not relieve any source from the payment of emission fees for any previous year.
 - [(6)] (E) Emission Calculation and Verification.
- [(A)] 1. Emission [C]calculation. All sources shall use the following hierarchy as a guide in determining the most desirable emission data to report to the department. If data is not available for an emission estimation method or an emission estimation method is impractical for a source, then the subsequent emission estimation method should be used in its place:

- [1.] A. Continuous Emission Monitoring System (CEMS) as specified in [paragraph (6)(B)1.] subparagraph (3)(E)2.A. of this rule;
- [2.] B. Stack tests as specified in [paragraph (6)(B)2.] sub-paragraph (3)(E)2.B. of this rule;
 - [3.] C. Material/mass balance;
- [4.] **D.** AP-42 (Environmental Protection Agency (EPA) Compilation of Air Pollution Emission Factors) or FIRE (Factor Information and Retrieval System) (as updated);
- [5.] E. Other EPA documents as specified in [paragraph (6)(B)3.] subparagraph (3)(E)2.C. of this rule;
 - [6.] F. Sound engineering calculations; or
- [7.] **G.** Facilities shall obtain department pre-approval of emission estimation methods other than those listed in *[paragraphs (6)(A)1.-6.]* **subparagraphs (3)(E)1.A.-F.** of this rule before using any such method to estimate emissions in the submission of an EIQ. The department will approve or deny requests by December 31 if submitted in writing by September 1.
- [(B)] 2. Emission [V]/verification. The director reserves the authority to review and approve all emission estimation methods used to calculate emissions for the purpose of filing an EIQ for accuracy, reliability and appropriateness. Inappropriate usage of an emission factor or method shall include, but is not limited to: using emission factors not representative of a process, using equipment in a manner other than that for which it was designed for in calculating emissions, or using a less accurate emission estimation method for a process when a facility has more accurate emission data available. Additional requirements for the use of a specific emission estimation method include:
 - [1.] A. Continuous Emission Monitoring System (CEMS).
- [A.] (I) CEMS must be shown to have met applicable performance specifications during the period for which data is being presented.
- [B.] (II) CEMS data must be presented in the units which the system was designed to measure. Additional data sets used to extrapolate CEMS data must have equal or better reliability for such extrapolation to be acceptable.
- [C.] (III) When using CEMS data to estimate emissions, the data must include all parameters (i.e. emission rate, gas flow rate, etc.) necessary to accurately determine the emissions. CEMS data which does not include all the necessary parameters must be reviewed and approved by the director or local air pollution control authority before it may be used to estimate emissions;
 - [2.] B. Stack tests.
- [A.] (I) Stack tests must be conducted on the specific equipment for which the stack test results are used to estimate emissions.
- [B.] (II) Stack tests must be conducted according to the methods cited in 10 CSR 10-6.030, unless an alternative method has been approved in advance by the director or local air pollution control authority.
- [C.] (III) Stack tests will not be accepted unless the choice of test sites and a detailed test plan have been approved in advance by the director or local air pollution control authority.
- [D.] (IV) Stack tests will not be accepted unless the director or local air pollution control authority has been notified of test dates at least thirty (30) days in advance and thus provided the opportunity to observe the testing. This thirty (30)-day notification may be reduced or waived on a case-by-case basis by the director or local air pollution control authority.
- [E.] (V) Stack test results which do not meet all the criteria of [subparagraphs (6)[B]2.A.-D.] parts (3)(E)2.B.I.-IV. of this rule may be acceptable for estimating emissions, but must be submitted for review and approval by the director or local air pollution control authority on a case-by-case basis; and
- [3.] C. EPA documents. Other EPA documents may be used to estimate emissions if the emission factors are more appropriate or source specific than AP-42 or FIRE. Newly developed EPA emission

factors must be published by December 31 of the year for which the facility is submitting an EIQ.

- [(7)] (F) Emission Fee Auditing/Adjustment.
- [(A)] 1. The department may conduct on-site detailed reviews (audits) of EIQs and supporting documentation as the director deems necessary.
- [(B)] 2. The department may make emission fee adjustments when—
 - [1.] A. Clerical or arithmetic errors have been made;
- [2.] **B.** Submitted documentation is not supported by inspections or audits;
- [3.] C. Emissions estimates are modified as a result of emission verification or audits:
- [4.] **D.** Credit has been incorrectly applied for an emissions fee paid to a local air pollution control agency; or
- [5.] E. The department shall not be limited by [paragraphs (7)(B)1.-4.] subparagraphs (3)(F)2.A.-D. of this rule in making emission fee adjustments.
- [(8)] (G) Request for Additional Fees and Emission Fee Refunds.
- [(A)] 1. A maximum two (2)-year review period, beginning on the date received, shall exist for all EIQ submissions. If an EIQ review indicates that additional emission fees are required, the department will notify the source in writing and request that additional fees be paid within forty-five (45) days. The notification shall state the reason for the additional fees and the amount due. If after forty-five (45) days the additional fees have not been paid, then enforcement action may be taken against the source to recover the additional fees.
- [(B)] 2. Emission [F]fee [R]refunds. Overpayment of emission fees shall be refunded to the source. The refund shall be accompanied by a letter stating the reason for the refund and the amount refunded. There shall be a two (2)-year time limit, beginning on the date the EIQ is received, for emission fee refunds. Refunds on EIQs exceeding the two (2)-year time limit shall only be considered upon written request by the source and if approved by the director.
- (4) Reporting and Record Keeping. Owners or operators shall maintain records containing sufficient information to demonstrate compliance with all applicable emission fee rule requirements as specified in subsections (3)(A) and (B). All data collected and recorded in accordance with the provisions of this rule shall be retained by the owner or operator for not less than five (5) years after the end of the calendar year in which the data was collected and all these records shall be made available to the director upon his/her request.

(5) Test Methods. (Not Applicable)

AUTHORITY: section 643.050, RSMo 2000. Original rule filed June 13, 1984, effective Nov. 12, 1984. For intervening history, please consult the Code of State Regulations. Amended: Filed May 15, 2003.

PUBLIC COST: This proposed amendment will result in an annualized aggregate loss of revenue of two hundred fifty thousand twelve dollars (\$250,012) for the Department of Natural Resources. This loss of revenue takes into account an annualized aggregate cost savings of forty-one thousand nine hundred ten dollars (\$41,910) for other public entities. Note attached fiscal note for assumptions that apply.

PRIVATE COST: This proposed amendment will result in an annualized aggregate cost savings of two hundred fifty thousand twelve dollars (\$250,012) for private entities. Note attached fiscal note for assumptions that apply.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: A public hearing on this proposed amendment will begin at 9:00 a.m., July 24, 2003. The public hearing will be held at Drury Inn & Suites, Ballroom, 11980 Olive Blvd., Creve Coeur, Missouri. Opportunity to be heard at the hearing shall be afforded any interested person. Written request to be heard should be submitted at least seven (7) days prior to the hearing to Director, Missouri Department of Natural Resources' Air Pollution Control Program, 205 Jefferson Street, PO Box 176, Jefferson City, MO 65102-0176, (573) 751-4817. Interested persons, whether or not heard, may submit a written statement of their views until 5:00 p.m., July 31, 2003. Written comments shall be sent to Chief, Planning Section, Missouri Department of Natural Resources' Air Pollution Control Program, 205 Jefferson Street, PO Box 176, Jefferson City, MO 65102-0176.

FISCAL NOTE PUBLIC ENTITY COST

I. RULE NUMBER

Title: 10 - Department of Natural Resources

Division: 10 - Air Conservation Commission

Chapter: 6 - Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

Type of Rulemaking: Proposed Amendment

Rule Number and Name: 10 CSR 10 - 6.110 Submission of Emission Data, Emission Fees and Process

Information

II. SUMMARY OF FISCAL IMPACT

	Estimated Cost of Compliance in the
Affected Agency or Political Subdivision	Aggregate
Misc. Public Entities (listed below)	\$41,910 Savings
Missouri Dept. of Natural Resources	\$250,012 Reduction In Revenue

Cost estimates are reported as annualized aggregates.

III. WORKSHEET

	FY2004*	FY2005	FY2006	FY2007	FY2008	FY2009
EIQ Fees	\$1,174,101	\$1,185,842	\$1,197,700	\$1,209,677	\$1,221,774	\$1,233,992
FY2010_	FY2011	FY2012	FY2013	FY2014*		
\$1,246,332	\$1,258,795	\$1,271,383	\$1,284,097	<u>\$0</u>		

Total Cost Over 10 Years	\$12,283,693
Annualized Aggregate Cost	\$1,228,369

		EIQ Fee Cost:	8
	FY2004	FY2005**	Annualized Aggregate
EIQ Fees (\$31.00 Fcc)	\$1,214,159	\$1,226,301	\$1,270,279

	FIQ Fee Costs		
	FY2004	FY2005**	Annualized Aggregate
EIQ Fees (\$30.00 Fee)	\$1,174,101	\$1,185,842	\$1,228,369

Aggregate EIQ Fee Cost Savings For This Amendment***	\$41,910
Reduction In Public Entity Fee Revenue For This Amendment***	\$291,922
Resulting Loss In Public Entity Fee Revenue For This Amendment***	\$250,012

^{*}See Assumption 3.

^{**}The first full fiscal year for this rulemaking is FY2005.

^{***}Difference in annualized aggregate costs using the \$31.00 fee with \$1.00 deducted for MoEIS.

List of Affected Entities:

Source Description	Number of Facilities
Gas & Electric	45
Sanitary Services	35
Hospitals	24
Rehabilitation Centers	2
Schools	9
Correctional Facility	5
National Security	6
Post Office	2
Transportation	3
Other	12
Totals	143

IV. ASSUMPTIONS

- 1. For the convenience of calculating this fiscal note over a reasonable time frame, the life of the rule is assumed to be ten (10) years although the duration of the rule is indefinite. If the life of the rule extends beyond ten years, the annual costs for additional years will be consistent with the assumptions used to calculate annual costs as identified in this fiscal note.
- 2. The public entity costs are fee collection estimates. The costs are based on the most recent data available to the department and are expected to be more accurate than previous fiscal notes for the same fiscal years.
- 3. All emission fees for calendar years are assumed to be submitted during the last six (6) months of the fiscal year. For example, costs for all calendar year 2003 emission fees are received by the Missouri Department of Natural Resources between January 1, 2004 and June 30, 2004.
- 4. Cost and affected entity estimates are based on data presently entered in the tracking systems of the Missouri Department of Natural Resources' Air Pollution Control Program. This data is subject to change as additional information is reviewed, updated, and entered.
- 5. Fees for public entities are based on \$31.00 per ton of regulated air pollutant with the one-time credit of \$1.00 per ton of regulated air pollutant deducted for the Missouri Emission Inventory System (MoEIS) project.
- 6. The emission fees paid by public entities may vary depending on their current information and their chargeable emissions with fees remaining relatively constant. However, new controls decrease the amount of their emission fees.
- 7. The Emission Inventory Questionnaire (EIQ) fees are assumed to increase by 1% from FY2004 to FY2005.
- 8. Compliance and EIQ preparation costs reported on EIQs are not included in this fiscal note because these costs are not a result of this rulemaking. Compliance and preparation costs have been included in fiscal notes for the rulemakings that implemented these requirements.
- 9. The aggregate reduction in public entity fee revenue for the Missouri Department of Natural Resources' Air Pollution Control Program is directly related to the difference in emission fees. The total reduction in revenue is equivalent to the amount of savings realized by both public and private entities paying emission fees.

FISCAL NOTE PRIVATE ENTITY COST

I. RULE NUMBER

Title: 10 - Department of Natural Resources	
Division: 10 - Air Conservation Commission	
Chapter: Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri	
Type of Rulemaking: Proposed Amendment	
Rule Number and Name: 10 CSR 10 - 6.110 Submission of Emission Data, Emission Fees and Process Information	

II. SUMMARY OF FISCAL IMPACT

class which would likely be affected	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
2,573 Facilities (listed below)	Listed below	\$250,012 Savings

Cost estimates are reported as annualized aggregates.

III. WORKSHEET

	FY2004*	FY2005	FY2006	FY2007	FY2008	FY2009
EIQ Fees	\$6,996,651	\$7,066,618	\$7,137,284	\$7,208,657	\$7,280,743	\$7,353,551

	FY2010	FY2011	FY2012	FY2013	FY2014*
ľ	\$7,427,086	\$7,501,357	\$7,576,370	\$7,652,134	\$0

Total Cost Over 10 Years	\$73,200,450
Annualized Aggregate Cost	\$7,320,045

		EIQ Fee Costs		
	FY2004	FY2005**	Annualized Aggregate	
EIQ Fees (\$31.00 Fee)	\$7,235,618	\$7,307,974	\$7,570,057	

		EIQ Fee Costs		
	FY2004	FY2005**	Annualized Aggregate	
EIQ Fees (\$30.00 Fee)	\$6,996,651	\$7,066,618	\$7,320,045	

	d #250.012
Total Aggregate Cost Savings For This Amendment***	4 5/200/01/2 1
I UM Aggregate Cost Swintes For This Amondment	W

^{*}See Assumption 3.

^{**}The first full fiscal year for this rulemaking is FY2005.

^{***}Difference in annualized aggregate costs using the \$31.00 fee with \$1.00 deducted for MoEIS.

List of Affected Entities:

SIC Code	SIC Description	Number of Facilities
01	AGRICULTURAL PRODUCTION CROPS	0
02	AGRICULTURAL PRODUCTION LIVESTOCK AND ANIMAL SPECIALTIES	2
07	AGRICULTURAL SERVICES	46
10	METAL MINING	11
12	COAL MINING	5
14	MINING AND QUARRYING OF NONMETALLIC MINERALS, EXCEPT FUELS	348
15	BUILDING CONSTRUCTION GENERAL CONTRACTORS AND OPERATIVE	18
16	HEAVY CONSTRUCTION OTHER THAN BUILDING CONSTRUCTION	5
17	CONSTRUCTION SPECIAL TRADE CONTRACTORS	4
20	FOOD AND KINDRED PRODUCTS	129
21	TOBACCO PRODUCTS	1
22	TEXTILE MILL PRODUCTS	1
23	APPAREL AND OTHER FINISHED PRODUCTS MADE FROM FABRICS	2
24	LUMBER AND WOOD PRODUCTS, EXCEPT FURNITURE	67
25	FURNITURE AND FIXTURES	24
26	PAPER AND ALLIED PRODUCTS	22
27	PRINTING, PUBLISHING, AND ALLIED INDUSTRIES	66
28	CHEMICALS, BRIQUETS, PAINTS	157
29	PETROLEUM REFINING AND RELATED INDUSTRIES	130
30	RUBBER AND MISCELLANEOUS PLASTICS PRODUCTS	56
31	LEATHER AND LEATHER PRODUCTS	6

SIC Code	SIC Description	Number of Facilities
32	STONE, CLAY, GLASS, AND CONCRETE PRODUCTS	338
33	PRIMARY METAL INDUSTRIES	55
34	FABRICATED METAL PRODUCTS, EXCEPT MACHINERY AND TRANSPORTATION	89
35	INDUSTRIAL AND COMMERCIAL MACHINER AND COMPUTER EQUIPMENT	Y 50
36	ELECTRONIC AND OTHER ELECTRICAL EQUIPMENT AND COMPONENTS	42
37	TRANSPORTATION EQUIPMENT	60
38	MEASURING, ANALYZING, AND CONTROLLING INSTRUMENTS	6
39	MISCELLANEOUS MANUFACTURING INDUSTRIES	21
40	RAILROAD TRANSPORTATION	0
41	LOCAL AND SUBURBAN TRANSIT AND INTERURBAN HIGHWAY PASSENGER	1
42	MOTOR FREIGHT TRANSPORTATION AND WAREHOUSING	21
44	WATER TRANSPORTATION	4
45	TRANSPORTATION BY AIR	4
46	PIPELINES, EXCEPT NATURAL GAS	20
47	TRANSPORTATION SERVICES	3
48	COMMUNICATIONS	2
49	ELECTRIC, GAS, SANITARY SERVICES, AND LANDFILLS	120
50	WHOLESALE TRADE-DURABLE GOODS	22
51	WHOLESALE TRADE-NON-DURABLE GOODS	162
52	LUMBER/HARDWARE	1
54	FOOD STORES	0
55	AUTOMOTIVE DEALERS AND GASOLINE SERVICE STATIONS	2
57	HOME FURNITURE, FURNISHINGS, AND EQUIPMENT STORES	0

SIC Code	SIC Description	Number of Facilities
59	MISCELLANEOUS RETAIL	1
60	BANK	0
63	INSURANCE CARRIERS	0
65	REAL ESTATE	0
70	HOTELS, ROOMING HOUSES, CAMPS, AND OTHER LODGING PLACES	Į.
72	PERSONAL SERVICES AND DRY CLEANERS	379
73	BUSINESS SERVICES	5
75	AUTOMOTIVE REPAIR, SERVICES, AND PARKING	7
76	MISCELLANEOUS REPAIR SERVICES	4
80	HEALTH SERVICES	39
82	EDUCATIONAL SERVICES	7
83	NURSE HOME	2
84	MUSEUMS, ART GALLERIES, AND BOTANICA AND ZOOLOGICAL GARDENS	AL 0
87	ENGINEERING, ACCOUNTING, RESEARCH, MANAGEMENT, AND RELATED	1
91	EXECUTIVE, LEGISLATIVE, AND GENERAL GOVERNMENT, EXCEPT FINANCE	0
92	CORRECTIONS	2
95	ADMINISTRATION OF ENVIRONMENTAL QUALITY AND HOUSING PROGRAMS	0
97	MILITARY	2
	Total Facili	ties 2,573

IV. ASSUMPTIONS

- 1. For the convenience of calculating this fiscal note over a reasonable time frame, the life of the rule is assumed to be ten (10) years although the duration of the rule is indefinite. If the life of the rule extends beyond ten years, the annual costs for additional years will be consistent with the assumptions used to calculate annual costs as identified in this fiscal note.
- 2. The private entity costs are fee collection estimates. The costs are based on the most recent data available to the department and are expected to be more accurate than previous fiscal notes for the same fiscal years.

- 3. All emission fees for calendar years are assumed to be submitted during the last six (6) months of the fiscal year. For example, costs for all calendar year 2003 emission fees are received by the Missouri Department of Natural Resources between January 1, 2004 and June 30, 2004.
- 4. Cost and affected entity estimates are based on data presently entered in the tracking systems of the Missouri Department of Natural Resources' Air Pollution Control Program. This data is subject to change as additional information is reviewed, updated, and entered.
- Fees for private entities are based on \$31.00 per ton of regulated air pollutant with the one-time credit of \$1.00 per ton of regulated air pollutant deducted for the Missouri Emission Inventory System (MoEIS) project.
- 6. The emission fees paid by private entities may vary depending on their current information and their chargeable emissions with fees remaining relatively constant. However, new controls decrease the amount of their emission fees.
- 7. The Emission Inventory Questionnaire (EIQ) fees are assumed to increase by 1% from FY2004 to FY2005.
- 8. Compliance and EIQ preparation costs reported on EIQs are not included in this fiscal note because these costs are not a result of this rulemaking. Compliance and preparation costs have been included in fiscal notes for the rulemakings that implemented these requirements.

Title 10—DEPARTMENT OF NATURAL RESOURCES Division 20—Clean Water Commission Chapter 6—Permits

PROPOSED AMENDMENT

10 CSR 20-6.010 Construction and Operating Permits. The commission is amending section (5), and adding section (14), and deleting the forms that follow this rule in the *Code of State Regulations*.

PURPOSE: This amendment creates a new option for permitting wastewater discharges from hydrostatic testing of new petroleum pipelines and storage tanks.

(5) Operating Permits.

(A) Persons who build, erect, alter, replace, operate, use or maintain any water contaminant source, point source or wastewater treatment facility which discharges to waters of the state shall obtain an operating permit from the department before any discharge occurs. The operating permit shall be issued to the owner/operator. Nondischarging facilities for the treatment or disposal of wastes, wastewater or residuals shall obtain permits as provided in 10 CSR 20-6.015. Persons who intend to discharge in accordance with section (14) of this rule are permitted by rule and may discharge without additional written approval from the department.

(14) Permit by Rule.

- (A) Hydrostatic Testing. Persons discharging water used for the hydrostatic testing of new petroleum-related oil and gas pipelines and storage tanks in the state of Missouri may discharge to waters of the state without first obtaining a permit if the discharge is *de minimis* (less than one thousand (<1,000) gallons) or the person takes the following steps:
- 1. Notification. The owner/operator must notify the department in writing of its intent to conduct hydrostatic test discharge(s) under this rule at least thirty (30) days prior to the first such discharge. This requirement may be met by a one (1)-time annual notification. Notice shall specify the source of water to be used in the hydrotest and shall identify the location(s) of the pipeline(s) and/or tank(s) to be tested.
- 2. Filing fee. Persons who intend to discharge in accordance with section (14) of this rule must pay a filing fee of twenty-five dollars (\$25) to the department with their notification above.
- 3. Discharge limits. The discharge must meet the following limits: <10 mg/l total petroleum hydrocarbons, <100 mg/l total suspended solids, and equal to or between 6.0 and 9.5 standard units pH.
- 4. Sampling and testing requirements. One (1) grab sample shall be taken per discharge during the first sixty (60) minutes of the discharge. The sample shall be analyzed for the pollutants limited by this rule. Total discharge volume shall be documented for each hydrostatic test discharge.
- 5. Analytical report. The owner/operator of the pipeline(s) and/or storage tank(s) on which the hydrostatic tests are performed shall submit an annual report summarizing each discharge, including date, time, test location, analytical results, and total discharge volume, in gallons, by October 28, of each year.
- 6. Exception reporting. If any of the sampling results from the hydrostatic test discharge show any violations of the following discharge limitations, written notification shall be made to the department within five (5) days of notification of analytical results. Notification shall indicate the date(s) of sample collection, the analytical results, and a statement concerning the revisions or modifications in management practices that are being implemented to address the violation of the limitation that occurred.
 - A. <10 mg/l total petroleum hydrocarbons;
 - B. <100 mg/l total suspended solids;

- C. pH equal to or between 6.0 and 9.5 standard pH units.
- 7. General requirement. The hydrostatic testing water shall not contain dyes or have a visible sheen indicating the presence of petroleum products.
- (B) The department may require a permit for these discharges if it determines that requiring a permit may better protect the quality of waters of the state.
- (C) The person(s) discharging under this rule may apply for a permit at any time.
- (D) This rule does not supersede nor eliminate liability for compliance with county and other local ordinances.
- (E) Persons discharging under this rule are not required to obtain a separate permit to construct and operate an oil-water separator to aid in meeting limits for hydrostatic wastewater.

AUTHORITY: section 644.026, RSMo [Supp. 1997] 2000. Original rule filed June 6, 1974, effective June 16, 1974. For intervening history, please consult the Code of State Regulations. Amended: Filed May 15, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: A public hearing on this proposed amendment will begin at 9:00 a.m., July 30, 2003. The public hearing will be held at the Holiday Inn Select Executive Center, 2200 I-70 Drive Southwest, Columbia, Missouri. Opportunity to be heard at the hearing shall be afforded any interested person. Written request to be heard should be submitted at least seven (7) days prior to the hearing to the Secretary of the Clean Water Commission, 205 Jefferson Street, PO Box 176, Jefferson City, MO 65102-0176, (573) 751-6721. Interested persons, whether or not heard, may submit a written statement of their views until 5:00 p.m. August 13, 2003. Written comments shall be sent to the Secretary of the Clean Water Commission, 205 Jefferson Street, PO Box 176, Jefferson City, MO 65102-0176.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 9—Internal Control System

PROPOSED AMENDMENT

11 CSR 45-9.030 Minimum Internal Control Standards. The commission is amending Appendix A.

PURPOSE: The purpose of the proposed amendment is to amend sections A, B, E, H, R and the Table of Contents of Appendix A which is incorporated by reference in this rule.

AUTHORITY: sections 313.004, 313.800 and 313.805, RSMo 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the Code of State Regulations. Amended: Filed May 6, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities more than five hundred dollars (\$500) in the aggregate. See attached fiscal note.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Public Safety, Missouri Gaming Commission, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this rule are requested to submit cost (estimated or actual, if available) with the comments. A public hearing is scheduled for July 30, 2003, at 10:00 a.m., in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

FISCAL NOTE PRIVATE ENTITY COST

J. RULE NUMBER

Title: 11 - DEPARTMENT OF PUBLIC SAFETY

Division: 45 - Missouri Gaming Commission

Chapter: 9 Internal Control System

Type of Rulemaking: Proposed Amendment

Rule Number and Name: 11 CSR 45-9.030 - Minimum Internal Control Standards

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
11	Licensed Riverboat Casinos	\$8,250
11	Licensed Riverboat Casinos	\$83,380
11	Licensed Riverboat Casinos	\$8,800

III. WORKSHEET

CHAPTER B – KEY CONTROLS

§ 4 Key Log

4.04 Some Casinos may have to add numbers to approximately 20% of all their keys.

Estimated startup costs of \$750 per Class A Licensee

Ongoing costs of \$750/yr per Class A Licensee

Total aggregate amount 11 Class A Licensees x \$750 = Total Aggregate Cost of \$8250/yr.

CHAPTER E - ELECTRONIC GAMING DEVICES (EGDs)

These new regulations promote potentially great, but unquantifiable cost savings to both Class A Licensees and the State by prevention of theft, error, and fraud.

§ 8 Statistics (11 CSR 45-5.220)

- 8.7 10% of one FTE @\$34,000 (Salary + Benefits) per casino: \$3400 per year x 11 casinos: \$37,400 aggregate ongoing costs per year
- 8.8 10% of one FTE @\$41, 800 (Salary = Benefits) per casino:

\$4180 per year x 11 casinos: \$45,980 aggregate ongoing costs per year

§ 14 Ticket Validation Systems – "Ticket In/Ticket Out" (TITO)

Implementation of TITO is **optional** - in the event a licensee elects to use TITO machines, costs would be significant, but unquantifiable.

§ 15 Redemption Kiosks

Implementation of TITO and Redemption Kiosks are optional - in the event a licensee elects to use TITO machines, costs would be significant, but unquantifiable, and Redemption Kiosks would be implemented to realize cost SAVINGS by eliminating employee costs.

CHAPTER R - FORMS

Duplicate Key Inventory Log

Affects 11 Casinos—each will have to create a new form Estimated one time start-up cost of \$100 0 on-going costs
Aggregate amount of \$1100.

EGD Drop Compartment Sweeps Log

Affects 11 Casinos —each will have to create a new form Estimated one time start-up cost of \$100 0 on-going costs
Aggregate amount of \$1100.

EGD Hand-Paid Jackpot Form

Affects 11 Casinos —each will have to create a new form/amend slot data systems Estimated one time start-up cost of \$500 0 on-going costs
Aggregate amount of \$5500.

EGD Sweeps Log

Affects 11 Casinos —each will have to create a new form Estimated one time start-up cost of \$100 0 on-going costs
Aggregate amount of \$1100.

IV. ASSUMPTIONS

Title 15—DEPARTMENT OF PUBLIC SAFETY Division 11—Missouri Gaming Commission Chapter 30—Bingo

PROPOSED RULE

11 CSR 45-30.540 Approval of Bingo Paraphernalia

PURPOSE: This rule clarifies items that must be approved by the commission, the party responsible for getting approval, and the approval process.

- (1) Licensed manufacturers shall submit all pull-tab flares and five (5) pull-tabs to the commission and obtain written approval from the commission prior to the delivery of such items to any licensed supplier to be made available for sale to organizations licensed to conduct bingo in this state.
- (2) Licensed manufacturers shall submit all coin boards, excluding the actual coins and prizes, or legible artwork of the coin board and five (5) pull-tabs to the commission and obtain written approval from the commission prior to the delivery of such items to any licensed supplier to be made available for sale to organizations licensed to conduct bingo in this state.
- (3) No unapproved pull-tabs or coin boards shall be provided to, or be possessed or used by, any licensed bingo organization in this state. Bingo paper that does not meet the definition contained in section 313.005, RSMo, shall not be provided to, or be possessed or used by, any licensed bingo organization. Any such bingo paper that may be provided to or possessed by a licensed bingo organization is declared contraband.

AUTHORITY: section 313.065, RSMo 2000. Original rule filed May 6, 2003.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Public Safety, Missouri Gaming Commission, Bingo Division, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this rule, are requested to submit the cost (estimated or actual, if available) with the comments. A public hearing is scheduled for July 30, 2003, at 10:00 a.m., in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 30—Bingo

PROPOSED RULE

11 CSR 45-30.550 Licensee's Duty to Report and Prevent Misconduct

PURPOSE: This rule establishes a licensee's duty to report and prevent misconduct associated with charitable gaming.

- (1) Licensees, workers, and employees of a licensee shall promptly report to the commission any facts which the licensee has reasonable grounds to believe indicate a violation of law (other than a traffic violation) or commission rule committed by any licensed bingo manufacturer, supplier, or organization, their workers or employees.
- (2) At no time shall any licensed bingo organization or its workers fail to take reasonable action to prevent or suppress any violent quarrel, disorder, brawl, fight, or other improper or unlawful conduct of any person at a bingo occasion.
- (3) In the event that a licensee, or a worker or employee of a licensee, knows that an illegal or violent act has been committed in association with bingo activities, the individual shall promptly report the occurrence to the commission (and local law enforcement officials, if applicable) and shall cooperate with authorities and agents of the commission during the course of any investigation of the occurrence.

AUTHORITY: section 313.065, RSMo 2000. Original ruled May 6, 2003

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Public Safety, Missouri Gaming Commission, Bingo Division, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this rule, are requested to submit the cost (estimated or actual, if available) with the comments. A public hearing is scheduled for July 30, 2003, at 10:00 a.m., in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 12—DEPARTMENT OF REVENUE

Division 10—Director of Revenue [Chapter 23—Motor Vehicle] Chapter 26—Dealer Licensure

PROPOSED AMENDMENT

12 CSR 10-[23.190] 26.180 Temporary Permits Sold by a Registered Missouri Motor Vehicle Dealer. The director proposes to amend the rule number, and sections (1), (3), (4) and (6).

PURPOSE: This rule is being amended for consistency and clarity.

(1) A registered dealer may provide no more than one (1) *[two (2)-piece set of]* temporary permit/s] per motor vehicle or trailer sold by his/her dealership. The temporary permits shall be effective for the number of days provided by law and shall be nonrenewable. No dealer shall sell a permit for use on any motor vehicle or trailer other than a motor vehicle or trailer sold by the dealer or his/her authorized employees at the dealer's own certified place of business except that a franchised motor vehicle dealer may issue a temporary permit for use on a motor vehicle the dealer delivers to a purchaser pursuant to a courtesy delivery arrangement made with another franchised dealer or manufacturer.

- (3) A registered dealer may charge no more than the fee prescribed by law for each *[set of]* temporary permit*[s]* as specified in section 301.140.4., RSMo.
- (4) Upon each sale of a *[set of]* temporary permit*[s]*, each dealer shall fully complete all information on the temporary permit*[s]* in accordance with Department of Revenue instructions and complete all appropriate records of issuance found within the booklet of permits. If the permit is issued pursuant to a courtesy delivery arrangement, the dealer issuing the permit must record the words courtesy delivery on the corresponding permit and on the permit record within the permit booklet. The information listed shall be true, accurate and complete. Temporary permits that are spoiled shall be marked void and kept as a part of the dealership's records. The records shall be maintained in booklet form for a period of at least three (3) years for inspection by law enforcement or Department of Revenue officials.
- (6) No temporary permit/s/ shall be issued for use on a motor vehicle unless there is a valid certificate of inspection and approval for the particular motor vehicle in accordance with section 307.380, RSMo. Dealers shall enter the true, accurate and complete motor vehicle inspection certificate number on the temporary permit record. No temporary permit shall be issued when the ownership document is a salvage certificate of title.

AUTHORITY: sections 301.140 and 307.380, RSMo [1986] 2000. This rule was previously filed as 12 CSR 10-23.190. Original rule filed Oct. 1, 1985, effective Dec. 26, 1985. Amended: Filed Nov. 13, 1986, effective Feb. 28, 1987. Amended: Filed Nov. 17, 1987, effective April II, 1988. Emergency amendment filed Oct. 26, 1990, effective Nov. 5, 1990, expired March 4, 1991. Amended: Filed July 2, 1990, effective Dec. 31, 1990. Moved and Amended: Filed May 14, 2003.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Revenue, Office of Legislation and Regulations, PO Box 629, Jefferson City, MO 65105. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 13—DEPARTMENT OF SOCIAL SERVICES Division 70—Division of Medical Services Chapter 98—Psychiatric/Psychology/Counseling/Clinical Social Work Program

PROPOSED RULE

13 CSR 70-98.010 Psychiatric/Psychology/Counseling/Clinical Social Work Program

PURPOSE: This rule establishes the regulatory basis for administration of the psychiatric/psychology/counseling/clinical social work program. This rule provides for such methods and procedures relating to the utilization of, and the payment for, care and services available under the Medicaid program as may be necessary to safeguard against unnecessary utilization of such care and services; to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such

care and services are available to the general population in the geographic area. The Department of Social Services is mandated by the Centers for Medicare and Medicaid Services to implement the provisions of the Health Insurance Portability and Accountability Act (HIPAA). In order to meet these mandates the Division of Medical Services (DMS) has redefined how psychiatrists, psychiatric clinical nurse specialists, psychologists, licensed clinical social workers, licensed professional counselors, federally qualified health centers (FQHCs), rural health centers (RHCs), and community mental health centers (CMHCs) must bill for services. HIPAA mandates that states allow providers to bill for services using the standard current procedural terminology (CPT) code sets, however, it does not require states to add coverage for services that it does not currently cover. DMS has not added coverage of services previously not covered, however, it is redefining limitations based on code definition, and clarification to Medicaid policy. Specific details of provider participation, criteria and methodology for provider reimbursement, recipient eligibility, and amount, duration and scope of services covered are included in the provider program bulletins and manual, which are incorporated by reference in this rule and available at the website www.dss.state.mo.us/dms.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

- (1) Administration. The Missouri Medicaid psychiatric/psychology/counseling/clinical social work program shall be administered by the Department of Social Services, Division of Medical Services (DMS). The services covered and not covered, the limitations under which services are covered, and the maximum allowable fees for all covered services shall be determined by DMS and shall be included in the provider program manual, which is incorporated by reference in this rule and available through the Department of Social Services, Division of Medical Services website at www.dss.state.mo.us/dms. Psychiatric/psychology/counseling/clinical social work services shall include only those which are clearly shown to be medically necessary. The division reserves the right to affect changes in services, limitations, and fees with notification to providers.
- (2) Persons Eligible. The Missouri Medicaid program pays for psychiatric/psychology/counseling/clinical social work services when furnished within the provider's scope of practice. The recipient must be eligible on the date the service is furnished. Recipients may have specific limitations for psychiatric/psychology/counseling/clinical social work services according to the type of assistance for which they have been determined eligible. It is the provider's responsibility to determine the coverage benefits for a recipient based on their type of assistance as outlined in the provider program manual. The provider shall ascertain the patient's Medicaid/MC+ and managed care or other lock-in status before any service is performed. The recipient's eligibility shall be verified in accordance with methodology outlined in the provider program manual.
- (3) Provider Participation. To be eligible for participation in the Missouri Medicaid psychiatric/psychology/counseling program, a provider must meet the licensing criteria specified for his or her profession and be an enrolled Medicaid provider.
 - (A) The enrolled Medicaid provider shall agree to:
- 1. Keep any records necessary to disclose the extent of services the provider furnishes to recipients; and

- 2. On request furnish to the Medicaid agency or State Medicaid Fraud Control Unit any information regarding payments claimed by the provider for furnishing services under the plan.
- (4) Covered Services. For all covered services, documentation of all stipulated documentation elements (referenced herein) are an essential and integral part of the service itself. No service has been performed if documentation requirements are not met.
- (A) Services furnished by a psychiatrist, psychiatric clinical nurse specialist, or psychologist are covered when furnished within the provider's scope of practice.
- 1. Services by a psychiatrist, psychiatric clinical nurse specialist may be furnished to eligible adults and children.
- 2. The psychiatrist, psychiatric clinical nurse specialist, or psychologist is working independently, or the employee of a federally qualified health center (FQHC), rural health center (RHC), or community mental health center (CMHC).
- 3. One (1) psychological testing service is covered per year per provider under the following criteria:
- A. When mental, psychoneurotic, or personality disorders are suspected;
- B. Self-administered or self-scored inventories are not covered as a testing service, but are included in the evaluation and management services, assessment, or as part of the total testing procedure:
- C. Ancillary personnel (psychometric technicians or other qualified persons) can only administer the pencil and paper portion and score psychological tests. The services of ancillary personnel cannot be billed separately, but are included in the reimbursement for testing, including all elements of testing: administration, scoring, interpretation, and report preparation;
- D. The psychiatrist, psychiatric clinical nurse specialist, or psychologist may bill up to four (4) one (1) hour units of testing procedure, accounting for the total components of the psychological testing service. This includes the time the provider spends in face-to-face consultation with the recipient, testing administered directly by the provider, but not the time when testing is administered by ancillary personnel, interpretation, and report preparation;
- E. If the testing is done over the course of several days, the testing procedure code may be reported on the date the report is completed
- (B) Services furnished by licensed or provisionally licensed professional counselor (LPC) or licensed or provisionally licensed clinical social worker (LCSW) are reimbursed by DMS when furnished within the provider's scope of practice to children under age twentyone (21).
- 1. The LCSW and LPC must be working independently or the employee of a FQHC, RHC, or CMHC.
- 2. By state statute, an LPC is unable to diagnose. Therefore, an independently enrolled LPC must maintain a copy of a diagnostic assessment from a Medicaid enrolled provider licensed to diagnose for all services provided. The diagnostic assessment from a Medicaid enrolled provider licensed to diagnose must have been completed not more than six (6) months prior to the initial date of service or more than eighteen (18) months prior to the date of any subsequently billed service.
- 3. Some services covered for children under age twenty-one (21) require prior authorization (PA). A list of services requiring PA can be found in the program manual at the DMS website at www.dss.state.mo.us/dms.
- (C) The assessment is a medical service. The assessment should be kept in the provider's file. Assessment services (psychiatric diagnostic interview exam) are limited to one (1) unit per provider per year. The single unit covers all components of the assessment. If the assessment is done over the course of several days, the assessment must be reported on the date the assessment is completed. If a child is in the legal custody of the Division of Family Services (DFS), a copy of the assessment shall be maintained in the DFS case file in

order for the provider to retain the reimbursement for the covered services.

- 1. An interactive psychiatric diagnostic exam may be billed in addition to an assessment when medically appropriate and is limited to one (1) unit per provider per year.
- 2. Each individual shall participate in an assessment that more fully identifies their needs and goals. The participation of family and other collateral parties (e.g., referral source, employer school, other community agencies) in assessment shall be encouraged, as appropriate to the age, guardianship, services provided, or wishes of the individual.
- A. The assessment shall assist in ensuring an appropriate level of care, identifying necessary services, and developing an individualized treatment plan. The assessment data shall subsequently be used in determining progress and outcomes. Documentation of the screening and assessment must include, but is not limited to, the following:
 - (I) Demographic and identifying information;
- (II) Statement of needs, goals, and treatment expectations from the individual requesting services. The family's perceptions are also obtained, when appropriate and available;
 - (III) Presenting situations/problem and referral source;
- (IV) History of previous psychiatric and/or substance abuse treatment including number and type of admissions;
 - (V) Health screening;
- (VI) Current medications and identifications of any medications allergies and adverse reactions;
- (VII) Recent alcohol and drug use for at least the past thirty (30) days and, when indicated, a substance use history that includes duration, patterns, and consequences of use;
 - (VIII) Current psychiatric symptoms;
- (IX) Family, social, legal, and vocational/educational status and functioning. The collection and assessment of historical data is also required unless short-term crisis intervention or detoxification are the only services being provided;
- (X) Current use of resources and services from other community agencies;
- (XI) Personal and social resources and strengths, including the availability and use of family, social, peer, and other natural supports; and
- (XII) Multi-axis diagnosis or diagnostic impression in accordance with the current edition of the *Diagnostic and Statistical Manual* of the American Psychiatric Association or the *International Classification of Diseases*, Ninth Revision, Clinical Modification (ICD-9-CM). The ICD-9-CM is required for billing purposes.
- (D) A treatment plan must be developed by the provider based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral, and developmental aspects of the recipient's situations and reflects the need for psychiatric/psychology/counseling/clinical social work services. Any services other than crisis intervention, assessment/diagnosis, or psychological testing that are performed prior to the completion of the treatment plan shall not be reimbursed by the MC+ or Medicaid programs or the recipient. If a child is in the legal custody of DFS, a copy of the treatment plan shall be provided to DFS in order for the provider to retain the reimbursement for the covered service(s).
- 1. Each person shall directly participate in developing his/her individualized treatment plan including, but not limited to, signing the treatment plan. A copy of the treatment plan shall be given to the parent or legal guardian of a child.
- 2. The individualized treatment plan shall reflect the person's unique needs and goals. The plan shall include, but is not limited to, the following:
 - A. Measurable goals and outcomes;
- B. Services, support, and actions to accomplish each goal/outcome. This includes services and supports and the staff member responsible, as well as action steps of the individual and other supports (family, social, peer, and other natural supports);

- C. Involvement of family, when indicated;
- D. Services needed beyond the scope of the organization or program that are being addressed by referral or services at another community organization, where applicable;
- E. Projected time frame for the completion of each goal/outcome; and
 - F. Estimated completion/discharge date for the level of care.
- 3. Progress toward treatment goals and outcomes shall be reviewed on a periodic basis.
- A. Each person shall directly participate in the review of their individualized treatment plan.
- B. The frequency of treatment plan reviews shall be based on the individual's level of care or other applicable program rules. The occurrence of a crisis or significant clinical event may require a further review and modification of the treatment plan.
- C. The individualized treatment plan shall be updated and changed as indicated.
- (E) A unit of service is defined in accordance with the current procedural terminology (CPT) definitions for a procedure code. The provider must furnish services within the following criteria for the following time measurements describing procedure codes.
- 1. A unit of service by CPT definition which represents twenty to thirty (20–30) minutes face-to-face with the recipient must include at least twenty (20) minutes face-to-face with the recipient. When less than thirty (30) minutes is spent face-to-face with the recipient, the remainder of the unit must be directed to the benefit of the recipient, including, but not limited to: report writing, note summary, reviewing treatment plan, etc.
- 2. A unit of service by CPT definition which represents forty-five to fifty (45–50) minutes face-to-face with the recipient must include at least forty-five (45) minutes face-to-face with the recipient. When less than fifty (50) minutes is spent face-to-face with the recipient, the remainder of the unit must be directed to the benefit of the recipient including, but not limited to: report writing, note summary, reviewing treatment plan, etc.
- 3. A procedure code which represents a time measure, whether insight oriented or interactive is covered for one (1) unit per day. The provider must choose the appropriate time measure to represent the service furnished.
- (F) Crisis intervention is an emergency service which is immediately available to a recipient, family member, or significant other or ameliorate emotional trauma precipitated by a specific event affecting the Medicaid eligible recipient.
 - 1. Services may be provided by telephone or face-to-face.
- 2. Services provided by telephone cannot be billed if the provider has a telephone hotline.
- 3. Telephone crisis intervention services must document the presenting problem, the scope of service provided, and resolution.
 - 4. Crisis intervention services cannot be scheduled.
- (G) Family therapy is defined as the treatment of family members as family unit together, rather than an individual "patient." The family unit is viewed as a social system that affects all its members.
- 1. When family therapy services are provided to a family (with or without the patient present), the session is billed as one (1) service (family unit), regardless of the number of individuals present in the session.
- 2. If family therapy with the patient present is directed at more than one (1) member of the family, the provider is limited to one (1) unit per day and may focus attention to different members of the family as needed during the session. The provider may not bill for each Medicaid/MC+ eligible member of the family separately. The provider may bill a modified family therapy procedure for additional family members beyond two (2) who participate in the family therapy session.
- 3. A family unit is not a group, and providers may not submit a claim for each eligible child attending the same session such as they would for group therapy.

- 4. If there is more than one (1) eligible child (biological, foster, adoptive, or any other family unit) and no child is exclusively identified in the session as the primary recipient of treatment, then the oldest child's identification number (Departmental Control Number (DCN)) must be used for billing purposes.
- 5. When a family consists of a Medicaid/MC+ eligible adult (e.g. parent, guardian) and a Medicaid/MC+ eligible child(ren) and the therapy is not directed at one (1) specific child, a psychiatrist, psychiatric clinical nurse specialist, or psychologist may direct treatment to the adult for the effective treatment of the family unit.
- A. If the adult is not eligible and the family therapy is directed at the adult and not the child, the service is not covered and must not be billed using the child's identification number (DCN).
- B. If the adult is not eligible, the provider may bill for the family therapy under the condition that the family therapy is directed to the exclusive benefit of the child and can be billed using a child's identification number (DCN).
- 6. Services of an LCSW and LPC are covered under the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) mandate for coverage of early and periodic screening, diagnosis, and treatment (EPSDT) services in accordance with the following:
- A. Services for a specific child in a family unit must be directed exclusively to the effective treatment of that child; and
- B. The issues of the parent may not be billed as a covered service by an LCSW or LPC.
- 7. Family therapy without patient present and family therapy with patient present are limited to one (1) unit of procedure code 90846 or 90847 per day per family.
- 8. Documentation of each service shall include members present, description of immediate issue addressed in therapy, identification of underlying roles, conflicts or patterns, description of therapist intervention, and progress towards goals.
- (H) Group therapy shall be directly related to the attainment of objectives as defined/specified in the written treatment plan.
- 1. Group therapy must consist of a group oriented process delivered to groups of three (3) but no more than eight (8) individuals.
 - 2. A maximum of three (3) units per day is covered.
 - 3. Group therapy is not covered in the home.
- 4. Group therapy may not be billed on the same date of service as family therapy unless the recipient is inpatient in a residential treatment facility or custodial care facility.
- A. A group home is defined as a child care facility which approximates a family setting, provides access to community activities and resources and provides care to no more than twelve (12) children.
- 5. When providing therapy to a group of children in a group home or a setting to provide a safe shelter for a group of individuals, group therapy is billed with a place of service "other."
- 6. Documentation of each service shall include members present, description of immediate issue addressed in therapy, identification of underlying roles, conflicts or patterns, description of therapist intervention, and progress towards goals.

(5) Non-Covered Services.

- (A) The following services are not covered under the psychiatric/psychology/counseling/clinical social work program:
- Services listed as non-covered on the psychiatric/psychological/counseling appendix;
 - 2. Tutoring;
- 3. Services provided by someone other than the enrolled provider;
- 4. Psychotherapy services to nursing facility residents when those services are provided in a nursing facility. Pharmacologic management including prescription is covered in a nursing facility;
 - 5. Services for diagnoses relating to mental retardation;
- 6. Electroshock therapy unless specified within the scope of practice;

- 7. Any service not documented with all stipulated elements covered by the documentation. Documentation must be completed within twenty-four (24) hours of the service being provided;
- 8. Any individual, family, or group therapy provided prior to the documentation of a treatment plan with all stipulated documentation elements; or
- 9. Any service provided by an LPC other than crisis intervention or assessment if the documentation of a current diagnostic assessment by a licensed provider as described previously is not documented in the record prior to the service being provided.
- (6) Non-allowed services under the psychiatric/psychology/counseling/clinical social work program (services are included as incidental to the providers cost of doing business and not allowed as separate billing to DMS or the recipient).
- (A) The entire time for a unit of therapy billed to DMS must be for the direct benefit of the recipient either in face-to-face therapy, report writing, note summary, reviewing treatment plan, etc., and includes the overhead costs or time associated with the cost of doing business. The following services are non-allowed:
- 1. Courtesy calls such as patient drop-in visits to give a progress report that were not scheduled and no therapy services were rendered:
- 2. Telephone consultations with colleagues or phone calls with the recipient that are not documented as crisis intervention;
 - 3. Missed appointments or failure to show;
- 4. Additional payment is not made for services that are performed after regularly scheduled office hours, on holidays, or on weekends;
 - 5. Services performed by nonlicensed, non-enrolled personnel;
- 6. Additional payment is not made for participation in discussion with colleagues for case planning or treatment including, but not limited to, staffing and Individual Education Plan (IEP).
- 7. Transportation and travel time or mileage to or from destinations, e.g., a provider may not bill a forty-five to fifty (45–50) minute unit of service and use ten (10) minutes of the time traveling to and from the service destination with the result of furnishing only thirty-five (35) minutes of therapy. In this case, the provider could only bill for the twenty to thirty (20–30) minute code;
- 8. Accompaniment to such places as the doctor's office, court, etc.;
 - 9. Shopping trips;
- 10. The paper/pencil portion of the psychological test administration provided by an individual under the direction or supervision of the enrolled psychologist.
- (7) Reimbursement. Payment will be made in accordance with the fee per unit of service as defined and determined by DMS. Providers must bill their usual and customary charge for psychiatric/psychology/counseling/clinical work services. Reimbursement will not exceed the lesser of the maximum allowed amount determined by DMS or the provider's billed charges.
- (A) When billing for assessment and testing services, the time selected for billing purposes includes face-to-face administration and report preparation. If the assessment or testing is done over several days, the assessment or testing components are combined and reported all on the last date of service.
- (B) In accordance with CPT definitions of service and Health Insurance Portability and Accountability Act (HIPAA) compliance for billing purposes, the fee structure and reimbursement has changed for some services. A list of covered procedures with the maximum allowable amount can be found in the psychiatric/psychological/counseling appendix on the DMS website at www.dss.state.mo.us/dms.
- (8) Documentation Requirements for Psychiatric/Psychology/Counseling/Clinical Social Work Services. Each date of service must contain the following documentation in the patient's medical record.

This documentation must be in narrative form, fully describing each session billed. A check-off list or pre-established form will not be accepted as sole documentation.

- (A) First and last name of recipient:
- 1. When family therapy is furnished, each member of the family included in the session must be identified. Description of immediate issue addressed in therapy, identification of underlying roles, conflicts or patterns, and description of therapist intervention;
- 2. When group therapy is furnished each service shall include the number of group members present, description of immediate issue addressed in therapy, identification of underlying roles, conflicts or patterns, and description of therapist intervention;
 - (B) The specific service rendered;
 - (C) Name of person who provided service;
- (D) The date (month/date/year) and actual begin and end time (e.g., 4:00-4:30 p.m.) for face-to-face services;
 - (E) The setting in which the service was rendered;
- (F) The pertinence of the service to the treatment plan (the plan of treatment is a required document in the overall records for the patient);
- (G) The individual's progress toward the goals stated in the treatment plan (progress notes);
- (H) An independent LPC must maintain a copy of a diagnostic assessment from a Medicaid enrolled provider licensed to diagnose. The assessment must have been completed not more then six (6) months prior to the initial date of service or more than eighteen (18) months prior to the date of any subsequently billed service;
- (I) When interactive therapy is billed, the provider must document the need for this service and the equipment, devices, or other mechanism of equipment used;
- (J) The documentation in the treatment plan, identified in subsection (4)(D) must be included in the patient's records and if applicable:
 - 1. Identification of other agencies working with the patient;
 - 2. Plans for coordinating services with other agencies; and
- 3. Identification of medications which have been prescribed for the patient must be included in the patient's record;
- (K) Documentation required by DMS does not replace or negate documentation/reports required by DFS for individuals in their care or custody. Providers are expected to comply with policies and procedures established by DFS and DMS. If a child is in the legal custody of DFS, the treatment plan shall be provided to DFS in order for the provider to retain the reimbursement for the covered service(s):
- (L) The requirement to document services and to release records to representatives of the Department of Social Services or the U.S. Department of Health and Human Services is found in 13 CSR 70-3.020 and 13 CSR 70-3.030.
- (9) Records Retention. Medicaid providers must retain for six (6) years from the date of service fiscal and medical records that coincide with and fully document services billed to the Medicaid program, and must furnish or make the records available for inspection or audit by the Department of Social Services or its representative upon request. Failure to furnish, reveal, and retain adequate documentation for services billed to the Medicaid program may result in recovery of the payments for those services not adequately documented and may result in sanctions to the provider's participation in the Medicaid program. This policy continues to apply in the event of the provider's discontinuance as an actively participating Medicaid provider through change of ownership or any other circumstance.

AUTHORITY: sections 208.152, 208.153, and 208.201, RSMo 2000. Original rule filed May 15, 2003.

PUBLIC COST: This proposed rule is expected to cost state agencies or political subdivisions \$7,724,823.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate. The state is going to begin paying for a service with psychologists, for certain members, which it has previously not paid. There is no new mandate on any provider that our fee is not intended to cover.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Office of the Director, Division of Medical Services, 615 Howerton Court, Jefferson City, MO 65109. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. If to be hand-delivered, comments must be brought to the Division of Medical Services at 615 Howerton Court, Jefferson City, Missouri. No public hearing is scheduled.

FISCAL NOTE

PUBLIC COST

I. RULE NUMBER

Rule Number and Name:	13 CSR 70-98.010 Psychiatric/Psychology/Counseling/ Clinical Social Work Program
Type of Rulemaking:	Proposed Rule

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Missouri Department of Social Services Division of Medical Services	\$7,724,823

III. WORKSHEET

Coverage of Medicaid enrolled adults by independently enrolled Medicaid psychologists for psychology services furnished with in the scope of practice of a psychologist.

Program Expenditures	
Total fee-for-service adults	293,206
Less Adults receiving psychiatric services	<u> </u>
	281,413
Adult utilization projected to be 50% of the utilization rate for	
children which is 16.28%	<u>x 8.14%</u>
Projected users	22,908
Average Cost of Adult Psychiatric Services	x \$337.20
Projected Expenditures	\$7,724,823

IV. ASSUMPTIONS

- The utilization of psychology services for adults is projected to be 50% of the utilization by children (16.28%) for psychology services.
- The cost for adult psychology services is projected to be equal to the average cost for adult users of psychiatric services.
- The number of eligible adults who are not receiving psychiatric services was multiplied by 8.14% to arrive at the number of adults who would utilize psychology services.
- The projected users were then multiplied by the cost/user to arrive at the estimated cost to provide psychology services to adults.

This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*, an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

he agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety (90)-day period during which an agency shall file its order of rulemaking for publication in the Missouri Register begins either: 1) after the hearing on the proposed rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of
Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.010 Health Requirements Governing the Admission of Livestock, Poultry and Exotic Animals Entering Missouri is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 399). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of
Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.020 Movement of Livestock, Poultry and Exotic Animals Within Missouri is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 399–400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of
Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.040 Animal Health Requirements for Exhibition is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE Division 30—Animal Health Chapter 6—Livestock Markets

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 277.160, RSMo 2000, the director amends a rule as follows:

2 CSR 30-6.020 Duties and Facilities of the Market/Sale Veterinarian **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 10—Wildlife Code: Commercial Permits:
Seasons, Methods, Limits

ORDER OF RULEMAKING

By the authority vested in the Conservation Commission under sections 40 and 45 of Art. IV, Mo. Const., the commission rescinds a rule as follows:

3 CSR 10-10.745 Swan Lake Migratory Bird Preservation Permit: Privileges, Requirements is rescinded.

This rule relates to hunting seasons and limits and is excepted by section 536.021, RSMo from the requirement for filing as a proposed rescission.

PURPOSE: The commission is rescinding this rule and closing the Swan Lake Zone to waterfowl hunting prior to the waterfowl hunting season due to harvest declines, and therefore, making the collection of parts no longer necessary under the provisions of the Swan Lake Migratory Bird Preservation Permit.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed Aug. 7, 1986, effective Jan. 1, 1987. Rescinded: Filed May 9, 2003.

SUMMARY OF COMMENTS: Seasons and limits are excepted from the requirement for filing as a proposed rescission under section 536.021, RSMo.

This proposed rescission filed May 9, 2003, effective June 2, 2003.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT Division 220—State Board of Pharmacy Chapter 2—General Rules

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.140 and 338.280, RSMo 2000, the board rescinds a rule as follows:

4 CSR 220-2.200 Sterile Pharmaceuticals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 2, 2003 (28 MoReg 10). No changes have been made to the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT Division 220—State Board of Pharmacy Chapter 2—General Rules

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000, the board adopts a rule as follows:

4 CSR 220-2.200 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 2, 2003 (28 MoReg 10–19). Changes have been made to the text of this rule. The rule is being reprinted in its entirety. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A total of twelve (12) written comments were received. In addition, a public hearing was held and comments were made by three (3) individuals who had not submitted written comments.

COMMENT: One (1) entity commented on subsection (1)(H) regarding the definition of compounding which they believe is too broad and subsection (1)(N) regarding expiration date, noting that the term "expiration date" should not be used when referencing compounded products, this term applies to manufactured products. They suggested that the term "beyond-use date" be used.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the comments and made changes to subsection (1)(H) and as well, established a definition of "beyond-use date" as a new subsection (1)(C).

COMMENT: One (1) entity commented on subsection (1)(P) stating that the requirement that a closed system made up of four (4) walls was unreasonable and that an isolation chamber would provide the same service.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (1)(P).

COMMENT: Two (2) entities commented on subsection (1)(Z), regarding the definition of risk levels stating that the American Society of Health Care Pharmacists (ASHP) Guidelines should be used to define the risk levels and questioning the board's intent in defining that risk level 1 and 2 products can be stored at room temperature, thus implying that risk level 3 products must be refrigerated. One entity also questioned the twenty-eight (28) hour stipulation in this section.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and adopted the definition of risk levels as provided by ASHP and further decided to change the twenty-eight (28) hours in paragraph (1)(Z)2. to forty-eight (48) hours.

COMMENT: Two (2) entities commented on subsection (4)(A) noting that the requirement for daily removal of used supplies was unreasonable, since many pharmacies compounded small amounts of products or did not compound every day.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made wording changes to this subsection.

COMMENT: One (1) entity commented on subsection (4)(B) noting that only finished but untested Risk Level 3 products should be quarantined.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to this subsection.

COMMENT: One (1) entity commented on subsection (5)(B) noting that the requirements for cleaning the controlled area were unnecessary unless the controlled area was used on a daily basis and that the rule does not allow for use of plexiglass or a glove box.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the first comment and added language to this section for cleaning the controlled area, which is not utilized on a daily basis. The board feels that the rule does not preclude the use of new technology, such as plexiglass or a glove box, to achieve the same result required by this subsection and thus disagreed with that comment.

COMMENT: One (1) entity commented on section (6) noting that required garb was costly and should not be required of risk level 1 and 2.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and deleted (1)(A) from this section and added language to previously numbered (1)(B) to clarify this issue.

COMMENT: Three (3) entities commented on subsection (7)(B) alleging that testing for each batch of Risk Level 2 products was unnecessary and expensive; that language in this section conflicted with statements in subsection (12)(B) and thus should be removed. RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (7)(B).

COMMENT: Three (3) entities commented on subsection (7)(C) noting that not all components have *United States Pharmacopoeia* (USP) monographs and other validations of chemical potency and purity are accepted and used.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to the language in this section.

COMMENT: One (1) entity commented on section (9) that the phrase "ingredient validation" is not defined and should be modified or removed.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and added clarifying language to section (9).

COMMENT: Two (2) entities commented on section (11) noting that expiration date is not an appropriate term for compounded products and that it should be "beyond-use date" and in addition, laboratory testing required in this section was excessive. Further, that in subsection (11)(C) the words "when necessary" be added to the end of the first sentence.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to this section to change the term expiration date to beyond-use date and require testing for stability and potency only on those products which have a beyond use of more than thirty (30) days and to add the words "when necessary" as requested.

COMMENT: Four (4) entities commented on subsection (12)(C) noting that the language can be interpreted to mean that intermediate products must be tested as well as the final product, which is redundant and costly.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (12)(C) to address the comments.

COMMENT: Two (2) entities commented on subsection (12)(D) noting that emergency dispensing should be clarified since requiring end product testing results prior to the release of these products would entirely preclude their use; pharmacies should be allowed to dispense the entire product, provided there is a mechanism for recalling dispensed products if testing yields unacceptable results.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made numerous changes to this subsection and in addition, moved this subsection to subsection (1)(O) of the rule under "definitions."

COMMENT: One (1) entity commented that the language in subsection (13)(A) was overly restrictive when applied to temperature and delivery services and submitted suggested language. RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made appropriate changes using the suggested language.

COMMENT: One (1) entity commented that the exemption provided for in section (15) was very vague and should be removed or reworded.

RESPONSE: After review of section (15), the board feels that specific processes for being exempt from this rule are included in this section and disagreed that the section is vague and unenforceable. No change was made based on this comment.

COMMENT: During the public hearing, one (1) entity stated that the rule should exempt home care pharmacies from this rule because of their long history of providing safe and optimal therapies to residents in long-term care facilities. The commenter further suggested that the board engage in a study with long-term care pharmacy providers to determine the nature and extent of rules needed for the preparation of sterile products in long-term care pharmacies.

RESPONSE: The board did not agree with the comment to exempt home care pharmacies from this rule because this would be an unequal application of the rule. The board believes that all pharmacies providing sterile pharmaceuticals must be held to the same minimum standards. No changes were made based on this comment.

COMMENT: Several entities commented that the Private Entity Costs were grossly underestimated as were the Public Entity Costs. RESPONSE AND EXPLANATION OF CHANGE: The board reviewed the cost statements and made changes to the annual costs by increasing the number of pharmacies to be affected but decreasing the number of batches, which will require full testing. The board also reviewed the public entity costs and deleted the cost of refractometers and increased the time to inspect. Public entity costs were also adjusted to indicate seven (7) inspectors, instead of six (6).

COMMENT: One (1) entity stated that implementation of this rule, if adopted, should be delayed to allow pharmacies to make system changes in order to comply.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and voted to establish the effective date of this rule as one year (twelve (12) months) after publication in the *Code of State Regulations*.

COMMENT: Several general comments were made. Several entities commented that the rule is anti-competitive and should be withdrawn. One entity stated that the entire approach was fundamentally flawed, with an over-reliance on product testing and the board should consider an alternative approach. One entity stated that section (11) would create a major constraint on practice.

RESPONSE: The board did not agree with these general comments given that most if not all of the standards portrayed in this rule come from model laws or national compendia. In addition, the board believes that any additional concerns of the ability to comply with these new standards were addressed through the changes made from comments received as well as the decision not to implement the rule for one year. The board also believes that changes made to section (11) and section (12) based on other comments addresses these concerns.

COMMENT: One (1) entity stated that the Robert Courtney case was the basis for this rule and it fails to meet the objectives. This entity also implied that board members had been motivated by competitive reasons and that Senator Bond had intervened on this issue. This entity stated that the language regarding advertising is a restriction on free speech.

RESPONSE: The board did not agree with the comments directed to the rule since there was no factual basis for the comments, that no specific information was provided to indicate that any portion of the rule was anti-competitive in any way, nor was there any specific information regarding the alleged restriction of free speech. Therefore, the board made no changes to the rule based on these comments.

4 CSR 220-2.200 Sterile Pharmaceuticals

(1) The provisions of sections (2)–(9) expire June 30, 2004.

(2) Definitions.

- (A) Biological safety cabinet—containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.
- (B) Class 100 environment—an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.
- (C) Compounded sterile drug—A sterile drug dosage form that has been prepared by a pharmacist, to include a commercially prepared sterile drug dosage form which has been altered by a pharmacist.
- (D) Cytotoxic Therapeutic Class—a pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system and the alteration of the host's inflammatory response system.
- (E) Parenteral—sterile preparation of drugs for injection through one (1) or more layers of skin.
- $\mbox{(F) Sterile pharmaceutical--a dosage form free from living microorganisms (aseptic).}$
- (3) Policy and Procedure Manual. A policy and procedure manual, as it relates to sterile products, shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis and shall include, but is not limited to, policies and procedures for any of the following services provided by the pharmacy:
 - (A) Clinical services;
 - (B) Cytotoxics handling, storage and disposal;
 - (C) Disposal of unused supplies and medications;
 - (D) Drug destruction and returns;
 - (E) Drug dispensing;
 - (F) Drug labeling/relabeling;
 - (G) Drug storage;
- (H) Duties and qualifications for professional and nonprofessional staff;
 - (I) Equipment;
 - (J) Handling of infectious wastes;
 - (K) Infusion devices and drug delivery systems;
 - (L) Investigational drugs;
- (M) Obtaining a protocol on investigational drugs from the principal investigator;
 - (N) Quality assurance procedures to include:
 - 1. Recall procedures;
 - 2. Storage and dating;
- 3. Educational procedures for professional staff, nonprofessional staff and patient;
- 4. Sterile procedures to include a log of the temperature of the refrigerator, routine maintenance and report of hood certification; and
 - 5. Sterility testing;
 - (O) Record keeping;
 - (P) Reference material;
 - (Q) Sanitation;
 - (R) Security;
 - (S) Sterile product preparation procedures; and
 - (T) Transportation.

(4) Physical Requirements.

(A) Space. The licensed pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded, sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of sterile pharmaceutical products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.

- (B) Equipment. The licensed pharmacy preparing sterile products shall have—
- 1. Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work area where critical objects are exposed and critical activities are performed; furthermore, the devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow systems of high efficiency particulate air filter (HEPA)-filtered air;
- 2. A sink with hot and cold running water and proper sewage disposal that is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
- 3. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;
- 4. When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
 - 5. Refrigerator/freezer with a thermometer;
 - 6. Temperature-controlled delivery container; and
 - 7. Infusion devices, if appropriate.
 - (C) Supplies.
- 1. Disposable needles, syringes and other supplies needed for aseptic admixture;
 - 2. Disinfectant cleaning solutions;
 - 3. Hand washing agent with bactericidal action;
 - 4. Disposable, lint free towels or wipes;
 - 5. Appropriate filters and filtration equipment;
 - 6. Oncology drug spill kit; and
 - 7. Disposable masks, caps, gowns and sterile disposable gloves.
- (D) Reference Library. The pharmacy shall have adequate current reference materials related to sterile products. Some suggested sources include: Handbook on Injectable Drugs, America Society for Hospital Pharmacists (ASHP); King's Guide to Parenteral Admixtures; United States Pharmacopeia (USP)/Negative Formulary (NF); American Hospital Formulary Service; Procedures for Handling Cytotoxic Drugs, American Society for Hospital Pharmacists (ASHP). In addition, the pharmacy shall maintain copies of current Occupational Safety and Health Administration (OSHA) requirements.

(5) Drug Distribution and Control.

- (A) Medication Record System. A pharmacy generated medication record system must be separate from the prescription file. The patient medication record system shall be maintained under the control of the pharmacist-in-charge for a period of sixty (60) days after the last dispensing activity. The medication record system, at a minimum, shall contain:
 - 1. Patient's full name;
 - 2. Date of birth or age;
 - 3. Weight;
 - 4. Sex;
 - 5. Sterile products dispensed;
 - 6. Date dispensed;
 - 7. Drug content and quantity;
 - 8. Patient direction;
 - 9. Identifying prescription number;
 - 10. Identification of dispensing pharmacist;
 - 11. Other drugs patient is receiving;
- 12. Known drug sensitivities and allergies to drugs and food; and
 - 13. Primary diagnosis.
- (B) Labeling (supplemental). Each sterile pharmaceutical dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:
- 1. Directions for administration including infusion rate, where applicable;
 - 2. Date of compounding;

- 3. Expiration date and time;
- 4. Identity of pharmacist compounding and dispensing;
- 5. Storage requirements;
- 6. Auxiliary labels, where applicable; and
- 7. Cytotoxic drug auxiliary labels, where applicable.
- (C) Records and Reports. The pharmacist-in-charge shall maintain access to, and submit as appropriate, records and reports required to insure the patient's health, safety and welfare. These reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the State Board of Pharmacy or its agents. Such shall include, at a minimum, the following:
 - 1. Purchase records;
 - 2. Policy and procedure manual;
 - 3. Training manuals, where applicable;
- 4. Policies and procedures for cytotoxic waste, where applicable;
- 5. Other records and reports as may be required by law and the rules of the State Board of Pharmacy; and
- 6. Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal or state laws, or both.
- (D) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all products shipped. A sterile pharmaceutical product must be shipped or delivered to a patient in appropriate temperature controlled delivery containers (as defined by USP standards) and assurances must be made that appropriate storage facilities are available. Chain of possession for the delivery of Schedule II controlled substances via couriers must be documented and a receipt required.
- (6) Cytotoxic Drugs. The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:
- (A) All cytotoxic drugs should be compounded in a vertical flow, Class II biological safety cabinet. If used for other products, the cabinet must be thoroughly cleaned;
- (B) Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves and gowns with tight cuffs;
- (C) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;
- (D) Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;
- (E) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual; and
- (F) Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Quality Assurance.

- (A) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications. These examinations shall include: visual inspection under a direct light source in the preparation of products in order to determine the presence of inappropriate particulate matter or signs of deterioration; policies and procedures for monitoring of sterile products whereby any untoward effects exhibited by a patient that may be due to the product, are reported to the pharmacy; and appropriate samples are collected and microbial tests are completed to ascertain the presence of microbial contamination of suspect products. Quality assurance procedures shall include:
 - 1. Recall procedures;

- 2. Storage and dating; and
- 3. Environmental procedures which include a log of the temperature of the refrigerator, routine maintenance and report of any hood certification.
- (B) Clean Room and Hood Certification. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209B or National Sanitation Foundation Standard 49 for operational efficiency at a minimum of every twelve (12) months. Certification records shall be maintained as a part of the pharmacy record.
- (C) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented.
- (D) Nonsterile Compounding. If bulk compounding is performed utilizing nonsterile chemicals, extensive end-product testing, as referenced in the Remington Reference Manual, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- (E) Expiration Dates. There shall be written justification of the chosen expiration date for compounded products. If a written standard is not available, a maximum of twenty-four (24) hours expiration date shall be used.
- (F) Quality Assurance Audits. There shall be documentation of quality assurance audits at regular, planned intervals and should include infection control and sterile technique audits.
- (8) Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when that compounding is restricted to the following:
- (A) The method of compounding utilizes compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.
- (B) The amount of compounding provided by the pharmacy is for emergency situations. An emergency is defined as—
- 1. Situations where the sterile compound is needed and is unavailable from or inconvenient to obtain from other sources;
- 2. Compounding will be provided to the patient immediately and used within a twenty-four (24)-hour period; and
- 3. Products are provided to the patient as a single dosage unit and the drug is not intended to be provided beyond an immediate emergency period.
- (9) This rule is not intended to include any pharmacy that provides sterile pharmaceuticals on a prescription order that has not been compounded by the pharmacy or had the packaging or labeling of the product altered by the pharmacy.
- (10) The provisions of sections (11)-(26) become effective July 1, 2004

(11) Definitions.

- (A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.
- (B) Batch: Compounding of multiple sterile product units in a single discrete process, by the same individuals, carried out during one (1) limited time period.
- (C) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

- (D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to NSF International standards.
- (E) Class 100 environment: an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.
- (F) Class 10,000 environment: An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.
 - (G) Clean room: A room-
 - 1. In which the concentration of airborne particles is controlled;
- 2. That is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room; and
- 3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.
 - (H) Clean zone: Dedicated space-
 - 1. In which the concentration of airborne particles is controlled;
- 2. That is constructed and used in a manner that minimizes the introduction, generation, and retention of particles inside the zone; and
- 3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary. This zone may be open or enclosed and may or may not be located within a clean room.
- (I) Compounding: For the purposes of this regulation, compounding is defined as in 4 CSR 220-2.400(1). Compounded sterile medications may include, but are not limited to, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.
- (J) Controlled area: For purposes of these regulations, a controlled area is the area designated for preparing sterile products. This is referred to as the buffer zone (i.e., the clean room in which the laminar airflow workbench is located) by the *United States Pharmacopoeia* (USP).
- (K) Critical area: Any area in the controlled area where products or containers are exposed to the environment.
- (L) Critical site: An opening providing a direct pathway between a sterile product and the environment or any surface coming into contact with the product or environment.
- (M) Critical surface: Any surface that comes into contact with previously sterilized products or containers.
- (N) Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system and the alteration of a host's inflammatory response system.
- (O) Emergency dispensing: Is a situation where a Risk Level 3 product is necessary for immediate administration of the product and no alternative product is available and the prescriber is informed that the product is being dispensed prior to appropriate testing. Documentation of the dispensing of the product, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.
- (P) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a Class 100 clean room.
- (Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling sys-

- tem provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.
- (R) Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.
- (S) Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the product and with the same container or closure system.
- (T) Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.
- (U) Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components and final sterile products prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity and sterility.
- (V) Repackaging: The subdivision or transfer of a compounded product from one container or device to a different container or device.
- (W) Sterile pharmaceutical: A dosage form free from living microorganisms.
- (X) Sterilization: A validated process used to render a product free of viable organisms.
 - (Y) Temperatures:
- 1. Frozen means temperatures between twenty below zero and ten degrees Celsius (-20 and 10°C) (four below zero and fourteen degrees Fahrenheit (-4 and 14°F)).
- 2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8° C) (thirty-six and forty-six degrees Fahrenheit (36 and 46° F)).
- 3. Room temperatures means room temperatures between fifteen and thirty degrees Celsius (15 and 30° C) (fifty-nine and eighty-six degrees Fahrenheit (59 and 86° F)).
- (Z) Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a product meeting predetermined specifications and quality attributes.
 - (AA) Definitions of sterile compounded products by risk level:
- 1. Risk Level 1: Applies to compounded sterile products that exhibit characteristics A., B., and C., stated below. All Risk Level 1 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Risk Level 1 includes the following:

A. Products:

- (I) Stored at room temperature and completely administered within forty-eight (48) hours after preparation; or
- (II) Stored under refrigeration for seven (7) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours; or
- (III) Frozen for thirty (30) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours.
- B. Unpreserved sterile products prepared for administration to one (1) patient or batch-prepared products containing suitable preservatives prepared for administration to more than one (1) patient.
- C. Products prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers.
- 2. Risk Level 2: Sterile products exhibit characteristic A., B. or C., stated below. All Risk Level 2 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product and with closed-system transfer methods. Risk Level 2 includes the following:

- A. Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30) days frozen or administered beyond forty-eight (48) hours after preparation and storage at room temperature.
- B. Batch-prepared products without preservatives that are intended for use by more than one (1) patient.
- C. Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder).
- 3. Risk Level 3: Sterile products exhibit either characteristic A. or B:
- A. Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization.
- B. Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(12) Policy and Procedure Manual.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2 and 3 products, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis.

(13) Personnel Education, Training and Evaluation.

- (A) Risk Level 1: All pharmacy personnel preparing sterile products must receive suitable didactic and experiential training.
- (B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training includes assessment of competency in all Risk Level 2 procedures via process simulation.
- (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training and experience to prepare Risk Level 3 products. The pharmacist knows principles of good compounding practice for risk level products, including—
 - 1. Aseptic processing;
- 2. Quality assurance of environmental, component, and end-product testing;
 - 3. Sterilization; and
 - 4. Selection and use of containers, equipment, and closures.

(14) Storage and Handling in the Pharmacy.

- (A) Risk Level 1 and 2: Solutions, drugs, supplies and equipment must be stored according to manufacturer or USP requirements. Refrigeration and freezer temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of products from boxes shall be done outside controlled areas. Removal of used supplies from the controlled area shall be done at least daily. Product recall procedures must permit retrieving affected products from specific involved patients.
- (B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, procedures include procurement, identification, storage, handling, testing, and recall of components and finished products. Finished but untested Risk Level 3 products must be quarantined under minimal risk for contamination.

(15) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disinfected prior to use. A workbench shall be recertified every six (6) months and when

- it is moved; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.
- (B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.
- (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a positive pressure barrier isolator. Access to the clean room must be limited to those preparing the products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized, calibrated, and documented according to manufacturer's standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

(16) Apparel.

- (A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers. Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.
- (B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn inside the controlled area at all times during the preparation of Risk Level 3 sterile products except when positive pressure barrier isolation is utilized. Attire shall consist of a low-shedding coverall, head cover, face mask, and shoe covers.

(17) Aseptic Technique and Product Preparation.

- (A) Risk Level 1: Sterile products must be prepared in a Class 100 environment. Personnel shall scrub their hands and forearms for an appropriate period at the beginning of each aseptic compounding process. Eating, drinking and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the product to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration and integrity before use. Only materials essential for aseptic compounding shall be placed in the workbench. Surfaces of ampules and vials shall be disinfected before placement in the workbench. Sterile components shall be arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc. Automated devices and equipment shall be cleaned, disinfected and placed in the workbench to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.
- (B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing formula, components, procedures, sample label, and final evaluation shall be made for each product batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile products, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end product for accuracy.
- (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet standards if available, as verified

by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining product integrity throughout the shelf life. Sterilization methods must be based on properties of the product

(18) Process Validation.

- (A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.
- (B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall cover all types of manipulations, products and batch sizes.
- (C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be maintained to validate all processes, procedures, components, equipment and techniques.

(19) Record Keeping.

- (A) Risk Level 1: The following must be documented:
- 1. Training and competency evaluation of pharmacy personnel involved in sterile product preparation;
 - 2. Refrigerator and freezer temperature logs;
 - 3. Certification of workbenches;
- 4. Copies of any manufacturer standards that are relied upon to maintain compliance with this rule; and
- 5. Other facility quality control logs as appropriate including all maintenance, cleaning, and calibration records.
- (B) Risk Level 2: In addition to Risk Level 1 requirements, records of any end-product testing and batch preparation records must be maintained.
- (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 products must include:
 - 1. Preparation work sheet;
 - 2. Sterilization records;
 - 3. Quarantine records, if applicable;
- 4. End-product evaluation and testing records as required in section (22); and
 - 5. Ingredient validation records as required in section (22).
- (D) All records and reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the board of pharmacy or its agents.

(20) Labeling.

- (A) Risk Level 1: Sterile products dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:
 - 1. Beyond-use date;
 - 2. Storage requirements;
 - 3. Any device specific instructions; and
 - 4. Auxiliary labels, when applicable.
 - (B) Risk Level 2: All requirements for Risk Level 1 must be met.
 - (C) Risk Level 3: All requirements for Risk Level 1 must be met.

(21) Beyond-Use Dating.

- (A) Risk Level 1: All sterile products must bear a beyond-use date. Beyond-use dates are assigned based on current drug stability information and sterility considerations.
 - (B) Risk Level 2: All requirements for Risk Level 1 must be met.
- (C) Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all expiration dates, including laboratory testing of product stability, pyrogenicity, partic-

ulate contamination and potency. Expiration dating not specifically referenced in the product's approved labeling or not established by product specific instrumental analysis, shall be limited to thirty (30) days. Beyond-use dating not specifically referenced in the products approved labeling or not established by product specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. Products maintaining beyond-use dating of greater than thirty (30) days shall have lab testing of product stability and potency.

(22) End-Product Evaluation.

- (A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection process.
 - (B) Risk Level 2: All Risk Level 1 requirements must be met.
- (C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of end-product sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch products shall be established if end-product testing results are unacceptable. All sterile products must be tested for sterility. All parenteral sterile products must also be tested for pyrogenicity. Sterile products compounded from nonsterile components must be quarantined pending results of end-product testing.
- 1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to one (1) of the USP methods.
- 2. Pyrogen/Endotoxin testing: Each sterile parenteral product prepared from nonsterile drug components shall be tested for pyrogen or endotoxin according to recommended USP methods.
- 3. Potency: The pharmacy shall have a procedure for a prerelease check of the potency of the active ingredients in the compounded sterile product prepared from nonsterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:
- A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis and other relevant qualities;
- B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;
- C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and
- D. The final potency is confirmed by instrumental analysis for sterile products that have been assigned a beyond-use date of more than thirty (30) days.
- (D) Emergency Dispensing of a Risk Level 3 Sterile Product: When a compounded Risk Level 3 product must be released prior to the completion of testing, the sterile product may be dispensed pending test results.

(23) Handling Sterile Products Outside the Pharmacy.

(A) Risk Level 1: The pharmacist-in-charge shall assure the environmental control of all sterile compounded products shipped. Sterile products shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile products. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of products with common storage characteristics and for specific products where unique storage conditions are required to retain adequate stability and product quality.

- (B) Risk Level 2: All requirements for Risk Level 1 must be met.
- (C) Risk Level 3: All requirements for Risk Level 1 must be met.

(24) Cytotoxic Drugs.

- (A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:
- 1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or an isolator. If used for other products, the cabinet must be thoroughly cleaned;
- 2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves and gowns with tight cuffs;
- 3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;
- 4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;
- 5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual;
- 6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.
- (25) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.
- (26) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.400 must be maintained.

REVISED PUBLIC COST: The cost to the board is estimated at ten thousand eight hundred fourteen dollars (\$10,814) versus the estimated twelve thousand five hundred ninety-seven dollars (\$12,597) which we submitted in the original estimate.

REVISED PRIVATE COST: The cost to private entities is estimated at \$1,351,600 during the first year of implementation of the rule and an estimated \$2,996,200 annually for the life of the rule versus the estimated \$1,351,600 during the first year of implementation of the rule and \$3,322,500 which we submitted in the original estimate.

REVISED FISCAL NOTE PUBLIC ENTITY COST

1. RULE NUMBER

Title: 4 -- Department of Economic Development

Division: 30 – State Board of Pharmacy

Chapter: 2 - General Rules

Type of Rulemaking: Proposed Rule

Rule Number and Name: 4 CSR 220-2,200 Sterile Pharmaceuticals

Revised March 27, 2003 by the State Board of Pharmacy

Affected Agency or Political Subdivision	Estimated Annual Cost of Compliance
State Board of Pharmacy (inspection of 29 Risk Level 1 Pharmacies)	\$1,452.00
State Board of Pharmacy (inspection of 61 Risk Level 2 & 3 Pharmacies)	\$6,110.00
State Board of Pharmacy (Inspector Training)	\$2,352.00
State Board of Pharmacy (Training Video)	\$200.00
State Board of Pharmacy (unknown costs estimates at \$100 per inspector)	\$700.
	£10.014.00

Total Annual Cost for the Life of the Rule \$10,814.00

WORKSHEET

Inspector time to inspect:

Inspector time to inspect:

Risk Level 1 - 29 Pharmacies

2 extra hours x \$25.04 per hour (average Inspector Salary)

x 29 pharmacics = \$1,452,32 (cents rounded down)

\$ 1,452.00

Risk Level 2 & 3 - 61 Pharmacies

4 extra hours x $$25.04 \times 61$ pharmacies = \$6,109.76 (cents rounded up)

\$ 6,110.00

Training for Inspectors

Seminar Cost (est) \$200.00

1 Night Hotel (est) \$ 90.00 (St. Louis CONUS) Meals 1 day (est) \$ 46.00 (St. Louis CONUS)

Unknown costs estimated at \$100 per in	nspector =	\$ 700.00
Purchase of Training Videos 1 set to be	shared (est)	\$ 200.00
Total	\$ 336.00 x 7 inspectors =	\$ 2,352.00

ASSUMPTIONS:

- 1. It will take an inspector approximately 2 extra hours of inspection time to inspect Risk Level 1 and 2 pharmacies providing sterile pharmaceutical products.
- 2. It will take an inspector approximately 4 extra hours of inspection time to inspect Risk Level 3 pharmacies providing sterile pharmaceutical products. This is the level where all non-sterile to sterile compounding of products will occur and will require the extra time for the inspector to inspect.
- 3. Refer to the table in Assumption 1 for breakdown of Risk Level 1 and 2 (combined) and Risk Level 3, used to calculate the number of pharmacies that will require extra inspection time.
- 4. It is anticipated that the total annual cost will recur each year for the life of the rule, may vary with inflation and are expected to increase annually at the rate projected by the Legislative Oversight Committee.

	REVISED FISCAL NOTE PRIVATE ENTITY COST	
I. RULE NUMBER		
	Economic Development	
	rd of Pharmacy	
Chapter: 2 – General Ru		
Type of Rulemaking:		
Rule Number and Name:	4 CSR 220-2,200 Sterile Pharmaccuticals	
Revised March 27, 2003 by II. SUMMARY OF FISCA	the State Board of Pharmacy AL IMPACT	
First Year of Implementat		Y
Estimate of the number		Estimate annual cost of
entities by class which wo		compliance with the rule
likely be affected by the adoption of the propose	-	by the affected entities:
rule:	u	
8	Class C: Long Term Care Pharmacies (barrier isolator - \$8,950)	\$71,600.00
8	Class C: Long Term Care Pharmacics (air conditioning, lighting, etc - \$4,000)	\$32,000.00
39	Pharmacies (construction of clean room - \$32,000)	\$1,248,000.00
	Total Cost Incurred During First Year of Implementation of the Rule	\$1,351,600.00

Annual Costs				
Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate annual cost of compliance with the rule by the affected entities:		
61	Pharmacies (apparel/clothing - \$250 per pharmacy each month)	\$183,000.00		
20	Pharmacies (testing of batches – 1,040 total batches per year x \$805 per batch) Sterility,	\$ 837,200.00		

	Potency and Pyrogenicity	
20	Pharmacies	\$ 1,976,000.00
20	(testing of batches – 4,160 total batches	\$ 1,5 × 0,0 00.00
	per year x \$475 per batch) Sterility and	
	Potency only	
	Total Annual Cost	© 2 006 200 00

Total Annual Cost for the Life of the Rule

\$ 2,996,200.00

ASSUMPTIONS:

1. Pharmacies must maintain compliance with the class of pharmacy which they will practice, both when they complete a new application and when the renewal is submitted. Pharmacies may also complete a form to add to or delete classifications from their license at any time. The statistics used in this fiscal note are taken from the PROMO licensing system, and is based on information provided to the Board by pharmacies.

Type of Pharmacy	Total #	% that will provide sterile products	Number that will provide sterile products	Risk level	-	reakdown k Level 2 & 3
Class B: Hospital	1	100%	1	1 DI 2/2		,
Outpatient + Class D Home Health				1 - RL 2/3		1
Class C: Long	231	25%	57.75	29 RL1	29	
Term Care + C combinations			rounded to	29 – RL 2 and 3		29
Class D: Home Health + D	31	75%	23	23 - RL 2 and 3		23
Combinations						
Class H: Sterile	8	100%	8	8 RL 2 and 3		8
Product						
Compounding + H		1				
combinations						
			90		29	61

- 2. There are categories of Risk Level 1, 2 and 3 in the field of sterile product compounding.
 - A. Risk Level 1: Applies to compounded sterile products that exhibit characteristics 1,2, and 3, stated below. All risk level 1 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Risk level 1 includes the following: (1) Products: (a) Stored at room temperature and completely administered within

- 48 hours after preparation or (b) Stored under refrigeration for seven days or less before complete administration to a patient over a period not to exceed 48 hours or (c) Frozen for thirty days or less before complete administration to a patient over a period not to exceed 48 hours. (2) Unpreserved sterile products prepared for administration to one patient or batch-prepared products containing suitable preservatives prepared for administration to more than one patient. (3) Products prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampuls) obtained from licensed manufactures into sterile final containers obtained from licensed manufacturers.
- B. Risk Level 2: Sterile products exhibit characteristic 1,2 or 3, stated below. All risk level 2 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product and with closed-system transfer methods. Risk Level 2 includes the following: (1) Products stored beyond seven days under refrigeration, stored beyond thirty days frozen or administered beyond 48 hours after preparation and storage at room temperature. (2) Batch-prepared products without preservatives that are intended for use by more than one patient. (3) Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder).
- C. Risk Level 3: Sterile products exhibit either characteristic 1 or 2: (1) Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization. (2) Products prepared by combining multiple ingredients--sterile or nonsterile--by using an open-system transfer or open reservoir before terminal sterilization.

It is estimated that 50% of Class C: Long Term Care Pharmacies will be at Risk Level 1 and 50% will be at Risk Levels 2-3.

It is estimated that 75% of Class D: Home Health and 100% of Class H: Sterile Product Pharmacies will be at Risk Levels 2 and 3.

Risk Level 1 pharmacies that prepare I.V's currently will already have the equipment required and are in compliance with the existing regulation.

These estimates are based on the fact that a licensee has the option to select the types of products that s/he chooses to compound. The licensee may choose to operate at a specific risk level, depending on his/her choice on issues such as beyond use date.

It is estimated that a total of 61 pharmacies could be affected by this rule. It is further estimated that 25% of these 61 pharmacies which is equal to 15 pharmacies, are involved in sterile product compounding which includes non-sterile to sterile product compounding.

During a review of the proposed rule and fiscal note in preparation for the final order of rulemaking, and after evaluation of information obtained from pharmacy inspectors, there are approximately 20 pharmacies which are involved in sterile product compounding,

- 3. There is a great variance in the type of products involved in sterile product compounding, including but not limited to, antibiotics, parenteral nutrition products, chemotherapy and pain management medications. There is also a wide range of scenarios and it is virtually impossible to determine an "average" per pharmacy.
- 4. Sterile to sterile compounding does not require additional testing above present regulatory requirements. Non-sterile to sterile compounding does require testing. Since no average can be calculated and the size of a batch can be virtually any size and given that the majority of pharmacies directly affected by the requirement are small or part-time compounders. A reasonable estimate for batch testing is set at one (1) batch per day per 5 day work week.

PRIVATE ENTITY COSTS:

1. Apparel/Clothing – Estimated at \$250 per month per pharmacy. The cost will be dependent on the number of individuals employed by the pharmacy.

 $$250 \times 61$ Pharmacies $\times 12$ months =

\$ 183,000.00

2. Testing: A batch is defined as one mixture or lot of one product. A batch can effectively be one (1) dose of a medication or it could consist of a large number of multiple doses of one product. Each batch must be tested for sterility, potency and pyrogenicity. The costs of testing will be determined by the number of batches prepared by a pharmacy. In many instances, 1 set of tests can be done. The Board of Pharmacy has no accurate method to measure the exact number of batches prepared in pharmacies. The number will be determined by the volume of compounding done in a pharmacy.

For the purposes of this fiscal note, it is estimated that an average sterile compounding pharmacy would prepare 1 batch per day.

Costs are:

Sterility Testing, per Batch \$175

Potency Testing \$300 per active ingredient

x 2 average active ingredients \$600

Pyrogenicity Testing (per batch) \$ 30.....Total per Batch \$805.00

1 Batch per day x 5 days x 52 weeks = 260 batches

260 batches x 20 pharmacies = 5,200 batches

It is further estimated that 20% of the 5,200 batches will require full testing i.e. 1,040

1,040 batches at full testing x \$805 per batch = \$837,200.00

It is further estimated that the remaining 4,160 batches would require only the sterility and potency testing at \$475.00

 $4,160 \text{ batches } \times \$475.00 =$

\$1,976,000.00

3. Class C: Long Term Care Pharmacies classified as a Risk Levels 2 and 3 may require the use of a Barrier Isolator. It is estimated that 50% of the 29 total Class C: Long Term Care pharmacies already comply with this rule and can be taken out of this equation. (29-14 = 15 pharmacies) This results in the estimated number of pharmacies affected to be 15 pharmacies. It is estimated that 50% of these 15 pharmacies may choose to purchase a Barrier Isolator in order to comply with new environmental standards. This would be 7.5 pharmacies, rounded to 8 pharmacies

8 Class C: Long Term Care Pharmacies x \$8.950 = \$71,600.00 Estimated additional costs for air conditioning, lighting, etc \$4,000 x 8 Pharmacies \$32,000.00

- 4. The following classes of pharmacies which are Risk Level 2 and 3, will be required to maintain a clean room if a barrier isolator is deemed insufficient for compounding needs:
 - Class B: Hospital/Outpatient
 - 7 Class C: Long Term Care Pharmacies
 - 23 Class D: Home Health
 - 8 Class H: Sterile Product Compounding

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A reasonable sized clean room is 8' x 10' x 10'. The current cost is \$40.00 per cubic foot. 8' x 10' x 10' x \$40.00 = \$32,000.00

39 pharmacies x \$32,000 =

\$1,248,000.00

Total Private Entity Costs

\$4,239,600.00

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT

Division 220—State Board of Pharmacy Chapter 2—General Rules

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000, the board amends a rule as follows:

4 CSR 220-2.400 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on January 2, 2003 (28 MoReg 20–21). Changes have been made to the text of this rule. The rule is being reprinted in its entirety. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A total of ten (10) written comments were received. In addition, a public hearing was held.

COMMENT: One (1) entity made general comments and did not direct any specific comment to a specific section of the rule. They stated that the Robert Courtney case was the basis for this amendment; that board members had been influenced by legislators and that one (1) or more board members may have been motivated by anticompetitive measures in promoting this amendment.

RESPONSE: The board did not agree with the comments directed to the rule since there was no factual basis for the comments, that no specific information was provided to indicate that any portion of the rule was anti-competitive in any way, and therefore, the board made no changes to the rule based on this comment.

COMMENT: One (1) entity stated that section (2) which is a broad restriction against the promotion of compounding products may invite a first amendment lawsuit.

RESPONSE AND EXPLANATION OF CHANGE: The original intent was to regulate against comparative, unsubstantiated claims between compounded medications and manufactured drugs, and the board feels that section (10) sufficiently addresses this issue. The board concurred with this comment and deleted the last sentence of section (2).

COMMENT: Two (2) entities commented that the definition of manufacturing in section (2) would preclude compounded prescriptions from being filled by Class J: Shared Service Pharmacies, as such activity would be considered manufacturing and that the prior rule's designation that promotion and marketing are considered manufacturing is in direct violation of the results of a recent lawsuit against the federal government which found that it was unconstitutional to limit a business's ability to promote its products. This should be corrected in the rule revision.

RESPONSE: The board disagreed with these comments and believes that the language would not prohibit compounding by Class J: Shared Service Pharmacies as long as there is a specific prescription for a specific patient involved in the process. The board disagreed with the comment regarding a pharmacy promoting its products. The board also agrees that it is a constitutional right of a pharmacy owner to promote his/her general pharmacy practices, as well as other beneficial services that the pharmacy offers. However, the promoting of specific products that have been compounded by a pharmacist, which are not the same as products that have been approved by the Food and Drug Administration (FDA), would be a violation of federal law. Any promotional claims concerning specific products of this type would be unsubstantiated. The board disagreed with this comment and no changes were made.

COMMENT: One (1) entity suggested the addition of an "and" in (5)(A)5., and that in (6)(A) the sentence beginning with "These responsibilitiesdispensing" should be deleted.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with these two (2) comments and changes were made accordingly.

COMMENT: One (1) entity suggested that in (6)(B), the term "reported" should be added to the last sentence regarding the drug monitoring system.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and the change was made.

COMMENT: Four (4) entities stated that subsection (5)(F) which requires the listing of all therapeutic ingredients be listed on the label is not feasible; that paragraph (6)(A)5., requiring adequate separation of quality control functions would be impossible for him to comply with since he is a one-man operation; and section (10) regarding the requirement that each compounded product be dispensed on a patient-specific prescription should be reviewed as concerns compounding for use by a physician or dentist in his/her office.

RESPONSE AND EXPLANATION OF CHANGE: The board agreed with the comment regarding therapeutic ingredients and changed the term "label" to "container." The board also agreed with the comment on paragraph (6)(A)5. and deleted that sentence. The board did not agree with the comment on section (10) and made no changes based on this comment. The practice of pharmacy is limited to the dispensing and/or compounding of drug products by prescription. Any activity in the area of compounding product outside this process could fall under the guise of manufacturing and become subject to the federal Food, Drug and Cosmetic Act.

COMMENT: One (1) entity commented that section (6) places the liability for proper preparation of manufactured drugs on pharmacies who have no direct contact with and no authority over manufacturers of drug products. Additionally, the language in paragraph (6)(A)2. is too restrictive since many commonly compounded drug products do not currently have USP monographs. The commenter suggested language to allow the pharmacist to satisfy ingredient quality requirements by utilization of the Certificate of Analysis. The commenter stated that in (6)(A)3. and 4. the language is too extreme and requires assurances that the pharmacist cannot provide.

RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to section (6) and its subsection based on these comments.

COMMENT: One (1) entity commented that in subsection (6)(B), the word "reported" should be added as clarification before the phrase "infection rates."

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and made the change. The board felt it should clarify the language on recalls and added language in subsection (6)(C) to more completely address the recall issue.

COMMENT: Three (3) entities commented on various portions of section (7), stating that the amendments to this rule favor manufacturers; it requires pharmacists to be guarantors of the quality of products they receive, an impossible burden, it would increase the cost of liability insurance; the private entity cost is more than five hundred dollars (\$500) in the aggregate; that it interferes with the physician's ability to prescribe appropriate therapies for their patients; that the word "food" should be "federal" and the entire new section (7) is outside the board's statutory authority.

RESPONSE AND EXPLANATION OF CHANGE: The board agreed with some of the comments and made appropriate changes in several areas of section (7), based on those comments, however they did not agree with the comments that section (7) is outside the board's statutory authority since the regulation of the practice of

pharmacy is clearly within the board's statutory authority under Chapter 338, RSMo. The board did not agree with the allegation that the language would prohibit the physician from prescribing appropriate therapies and noted that the intent of this language is not to bar different dosage forms but addresses the issue of making the same type of product. No change was made based on this comment.

COMMENT: Two (2) entities commented that section (10) restricts the compounding of products to patient-specific prescriptions, which may limit a patient's access to important medications during medical procedures where only a small amount of a compounded product would be used.

RESPONSE AND EXPLANATION OF CHANGE: The board disagreed with this comment because compounding, under federal law, must be done on a patient-specific prescription. The changes made to section (10) were not based on the comments, but on board review.

COMMENT: One (1) entity commented on several sections of the rule including section (1), subsection (5)(A), paragraph (5)(A)8., and sections (8), and (10) noting several minor wording changes. In addition, the commenter noted that throughout the rules, several terms are used such as "bulk compounded product," "batched product," "excess product" and "excess compounded product," all meaning the same thing. It was suggested that the board use the term "batched compounded product" and also provide a definition of this term

RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the comments and made appropriate changes throughout this rule and in addition, added a new section (3) to define a batch compounded product.

COMMENT: Several entities stated that the fiscal notes attached to this amendment were flawed.

RESPONSE: The board believes that the changes made to the amendment address the cost issue and the board did not see any additional costs.

4 CSR 220-2.400 Compounding Standards of Practice

- (1) Compounding is defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.
- (2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices.
- (3) Batch compounded product is defined as a product compounded in advance of receipt of a prescription or a product compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any product compounded in excess of the filling of an individual prescription. A batch is a specific quantity of product compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.
- (4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from

those applied to assigning expiration dates to manufactured drug products.

- (5) Compounding Area and Equipment Requirements.
- (A) The area(s) used for the compounding of drugs shall be maintained in a sanitary condition and shall be free of infestation by insects, rodents and other vermin. Trash shall be held and disposed of in a timely and sanitary manner.
- (B) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.
- (C) Equipment used in the compounding of drug products shall be of appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact ingredients, inprocess materials or drug products shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired.
- (6) Proper controls shall be maintained over drug products/ingredients, containers and container closures.
- (A) Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.
- (B) Pharmacists shall only receive, store or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors.
- (C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.
- (D) Drug products/ingredients, containers and container closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination.
- (E) Drug product/ingredient containers and container closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded drug beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.
- (7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.
- (A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:
- 1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
 - 2. Date of compounding;
 - 3. Identity of the compounding pharmacist;
- 4. A listing of the drug products/ingredients and their amounts by weight or volume;
- 5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;
- 6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and
- 7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.
- (B) Information related to and the methods of compounding shall be available upon request.

- (C) Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.
- 1. The compounding of drug products in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need, shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched product that represents a three (3)-month supply.
- 2. Creams, ointments, lotions, liniments or other compounded products intended for external use may be batched in the same manner as provided for in paragraph (5)(C)1. of this rule that represents a one (1)-year supply.
- (D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-use date.
- (E) Records as outlined in this rule shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.
- (F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the container of any product provided to a consumer.
- (8) Management of Compounding.
- (A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:
- 1. Personnel are capable and qualified to perform their assigned duties;
- 2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;
- 3. Reasonable assurance that processes are always carried out as intended or specified;
- 4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and
- 5. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.
- (B) The pharmacy is responsible for developing a drug monitoring system for compounded products. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services. This shall include but not be limited to reported infection rates, incidence of adverse drug reactions, incidence of recalls and complaints from prescribers or clients.
- (C) A recall must be initiated when a product is deemed to be misbranded or adulterated. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified and any recommended actions to ensure public health and safety.
- 1. In cases where the compounded product has the potential to harm the patient, the same recall notification, as provided for in this subsection, shall be provided to all patients that have received the recalled compounded product(s).
- 2. Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days.
- (9) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially avail-

- able Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.
- (10) Any alteration, change or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any drug product to be sold without a prescription is prohibited.
- (11) Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with drug products/ingredients, drug product containers, container closures and in-process materials, until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded.
- (12) Pharmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded products.
- (13) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.200 Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT Division 240 Public Services Commission

Division 240—Public Service Commission Chapter 120—New Manufactured Homes

ORDER OF RULEMAKING

By the authority vested in the Public Service Commission under section 700.040 and 700.115, RSMo 2000, the commission adopts a rule as follows:

4 CSR 240-120.140 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on March 17, 2003 (28 MoReg 547–548). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A hearing was held on April 23, 2003 at 9:00 a.m. in the Governor Office Building, 200 Madison Street, Jefferson City, Missouri. The Missouri Public Service Commission received one (1) comment on the proposed rule.

COMMENT: A manufactured home manufacturer recommended that the due date for remission of a fee that equals the number of new manufactured homes delivered or sold to dealers in the state of Missouri, multiplied by thirty dollars (\$30), and for the submitting of monthly delivery reports, other filings, or other documentations required by the commission be extended from the tenth to the twentieth day following the month in which new manufactured homes were delivered or sold to dealers in the state of Missouri.

RESPONSE AND EXPLANATION OF CHANGE: The commission agrees to this change.

4 CSR 240-120.140 New Manufactured Home Manufacturer's Inspection Fee

(2) Manufacturers of new manufactured homes shall remit to the director on a monthly basis an amount that equals the number of new manufactured homes delivered or sold to dealers in the state of Missouri, multiplied by thirty dollars (\$30). Each manufacturer shall submit said fee with any monthly delivery reports, or other filing, or documentation as may be required by the commission. Said fee shall be received no later than the twentieth day following the month in which new manufactured homes were delivered or sold to dealers in the state of Missouri.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT

Division 240—Public Service Commission Chapter 123—Modular Units

ORDER OF RULEMAKING

By the authority vested in the Public Service Commission under section 700.040, RSMo 2000, the commission amends a rule as follows:

4 CSR 240-123.030 Seals is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 17, 2003 (28 MoReg 549–550). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 10—DEPARTMENT OF NATURAL RESOURCES Division 10—Air Conservation Commission Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

ORDER OF RULEMAKING

By the authority vested in the Missouri Air Conservation Commission under section 643.050, RSMo 2000, the commission amends a rule as follows:

10 CSR 10-6.100 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 16, 2002 (27 MoReg 2274–2276). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Missouri Department of Natural Resources' Air Pollution Control Program received comments from the U.S. Environmental Protection Agency (EPA).

COMMENT: The EPA commented that in paragraph (3)(D)3, the reference to 10 CSR 10-6.060(4)(A)2. should be 10 CSR 10-6.060(7)(C)2. In subparagraphs (3)(D)7.B., (3)(D)7.C. and paragraph (3)(E)3., the references to 10 CSR 10-6.060(8)(D) should be 10 CSR 10-6.410. In paragraph (3)(D)8., the reference to 10 CSR 10-6.060(8)(C) should be 10 CSR 10-6.410.

RESPONSE AND EXPLANATION OF CHANGE: The department's Air Pollution Control Program agrees and has changed the noted references.

10 CSR 10-6.100 Alternate Emission Limits

(3) General Provisions.

(D) Criteria for Approval.

- 1. An Alternate Emission Limits Permit application must demonstrate that the proposed control will not cause total emissions from the source operations to exceed the level of emissions determined in subsection (3)(C).
- 2. Applicants desiring to make use of emission reductions occurring at another installation must demonstrate that the emissions have occurred or will occur prior to the commencement of the alternate emission limit; and that the owner or operator of the installation from which emission reductions are obtained has entered a legally binding and enforceable agreement approved by the director or changed the installation's permit conditions to limit emissions of VOCs at the specified source operations to the levels and rates identified in the application.
- 3. No alternate emission limit may be approved which allows a new or modified source operation to exceed New Source Performance Standards (NSPS) in 10 CSR 10-6.070 or 40 CFR part 60 or the requirement for lowest achievable emission rate (LAER) in 10 CSR 10-6.060(7)(C)2.
- 4. No alternate emission limit may be approved which allows emissions of a hazardous pollutant from any source operation to exceed National Emission Standards for Hazardous Air Pollutants (NESHAPS) in 10 CSR 10-6.080 or 40 CFR part 61 or which allows emissions of a hazardous pollutant to increase for which a standard has not yet been promulgated.
- 5. An application proposing an emission decrease from process curtailments or source operation shutdowns will not be approved if the proposed decrease will be negated by countervailing emission increases occurring at other installations in the same area in response to the applicant's process curtailment or shutdown.
- 6. An application proposing to use emission reductions from the shutdown of an installation will not be approved. These reductions are available only to the owner of the shutdown installation for replacement purposes or to new or modified installations in the area as growth margin.
- 7. An application proposing to make use of emission reductions which occurred prior to applying for an alternate emission limit permit is subject to the following time constraints:
- A. No application may be approved involving emission reductions which occurred prior to January 1, 1980 in the St. Louis metropolitan area or January 1, 1977 in the Kansas City metropolitan area unless the emission reductions were accounted for in the respective base year inventory as banked emission reduction credits;
- B. For emission reductions which occurred between January 1, 1980 in St. Louis or January 1, 1977 in Kansas City and December 11, 1982, applications must be submitted within nine (9) months (September 11, 1983) after December 11, 1982 unless credit for the emission reductions is banked in accordance with 10 CSR 10-6.410; and
- C. For emission reductions which occur after the effective date (December 11, 1982), applications must be submitted within one (1) year of the emission decrease unless credit for the emission reductions is banked in accordance with 10 CSR 10-6.410.
- 8. No application may be approved which proposes to use emission reductions which previously have been used to offset emission increases as described in 10 CSR 10-6.410 or to net against emission increases as discussed in the definitions of major modification and net emission increase in 10 CSR 10-6.020. Emission reductions used to create an alternate emission limit are likewise for the duration of the alternate emission limit not eligible to be banked, used for offset purposes or used to net against emission increases.

- 9. An application must include an expeditious schedule of implementation that adheres as closely as possible to any compliance dates the source operation would otherwise be subject to.
- 10. An application will be approved only if it is determined that the alternate emission limit will not interfere with attainment and maintenance of the ambient air quality standard or create any public nuisance.
- 11. All alternate emission limits that are approved by the director will not be considered federally enforceable (and will not shield a source from the federal obligation to comply with the underlying emission limits) by the United States Environmental Protection Agency (EPA) until submitted to the EPA and approved by the EPA. (E) Quantification of Emission Reductions.
- 1. In cases where the director determines that the emission reduction estimates made by the applicant are uncertain, the director may calculate alternative emission limitations based on other estimates
- 2. If necessary to quantify emission reductions to be used in an alternate emission limit, the director may require source tests, continuous monitors or any other acceptable means of measurement before and after reductions occur.
- 3. To quantify emission reductions which have already occurred, the director will rely on the installation's emissions reported in the base year inventory used to project attainment of the ozone standard in the State Implementation Plan and the emission inventory taken the twelve (12) months following the reduction or if credits for the emission reductions were banked in accordance with 10 CSR 10-6.410, the director will rely on the documentation provided at the time the credits were banked.

Title 15—ELECTED OFFICIALS Division 30—Secretary of State Chapter 45—Records Management

ORDER OF RULEMAKING

By the authority vested in the secretary of state under sections 59.319 and 109.221, RSMo 2000, the secretary amends a rule as follows:

15 CSR 30-45.030 Local Records Grant Program Administration is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 422). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 20—Division of Environmental Health and Communicable Disease Prevention Chapter 8—Lead Program

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Health and Senior Services under sections 701.340 through 701.349, RSMo Supp. 2001, the director adopts a rule as follows:

19 CSR 20-8.030 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on March 3, 2003 (28

MoReg 422–428). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received three (3) comments on the proposed rule.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, requested that the rule be revised to underscore the importance of making considerable efforts to further define smaller geographic high-risk areas.

RESPONSE AND EXPLANATION OF CHANGE: Paragraph (2)(C)1. will be changed to reflect the importance of those efforts.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, requests that paragraph (2)(E)2. be reconsidered as it may create "provider backlash" against lead screening.

RESPONSE AND EXPLANATION OF CHANGE: Paragraph (2)(E)2. is deleted as the department agrees that the language may cause confusion and unnecessary negative implications.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, suggests that the rule specify how providers and communities will be notified of risk designation and the importance of screening in high-risk areas.

RESPONSE: Subsection (2)(B) provides for annual publishing of designated high-risk areas. The subsection also states that this publication shall be made available on the DHSS website. No changes have been made to the rule as a result of this comment.

19 CSR 20-8.030 Lead Poisoning Assessment, Testing, Follow-Up, and Reporting

- (2) Criteria Designating Geographic Areas as High-Risk for Lead Poisoning.
 - (C) Reconfiguring Geographic Areas.
- 1. At the time of the annual lead data analysis described in subsection (2)(A) of this rule, the department will make efforts to reconfigure geographic areas into smaller areas, where at all possible, based on available census data, official population estimates, meeting acceptable margins of residential identification error for all lead tested children, new technology or software making it possible to accurately identify smaller areas, or an acceptable data-substantiated proposal made by a local health agency, as described in paragraph (2)(C)2. of this rule.
- 2. A local health agency may propose reconfiguration of the size or distribution of its high-risk areas, by submitting the proposal to the department by January 1 of each year. Supporting evidence must accompany the proposal. If the department adopts the proposal, it will by published in the annual listing.
- (E) Redesignation of Area Risk Status. The department may redesignate a previously designated high-risk geographic area, either totally or in part, as non-high-risk for lead poisoning, or conversely, a previously designated non-high-risk geographic area may be redesignated, either totally or in part, as high-risk for lead poisoning based on the criteria in subsection (2)(A) of this rule or other new substantiated evidence.
- 1. Smaller geographic areas must be defined by easily recognized boundaries that are approved by the department such as, but not limited to, census tracts, city blocks, or a defined distance from a known lead hazard.
- 2. A local health agency may propose a redesignation of area risk status, by submitting the proposal to the department by January 1 of each year. Supporting evidence must accompany the proposal. If the department adopts the proposal, it will be published in the annual listing.

Title 19—DEPARTMENT OF HEALTH
AND SENIOR SERVICES
Division 30—Division of Health Standards and
Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 195.015 and 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.002 Schedules of Controlled Substances is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 429–434). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Health Standards and Licensure Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.011 Definitions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 434). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Health Standards and Licensure Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 195.030 and 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.015 Registrations and Fees is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 434–435). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH
AND SENIOR SERVICES
Division 30—Division of Health Standards and
Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.017 Registration Process is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 435–436). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH
AND SENIOR SERVICES
Division 30—Division of Health Standards and
Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.019 Registration Location is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 436). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Health Standards and Licensure Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.023 Registration Changes is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 436–437). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Health Standards and

Licensure Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.034 Security for Practitioners is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 437–438). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Health Standards and Licensure

Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department rescinds a rule as follows:

19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on March 3, 2003 (28 MoReg 438). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 40—Division of Maternal, Child and Family Health

Chapter 9—Universal Newborn Hearing Screening Program

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Health and Senior Services under section 191.937, RSMo 2000, the director amends a rule as follows:

19 CSR 40-9.020 Screening Methodologies and Procedures is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 438–439). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.300 Definitions for the Certificate of Need Process is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 157). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.300 Definitions for the Certificate of Need Process is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 157–159). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.400 Letter of Intent Process is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 159). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review
Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.400 Letter of Intent Process is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 159–160). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review
Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.410 Letter of Intent Package is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 160). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.410 Letter of Intent Package is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 160–161). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.420 Review Process is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 161). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.420 Review Process is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 161–162). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee

Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.430 Application Package is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 162). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.430 Application Package is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 163–164). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.450 Criteria and Standards for Long-Term Care is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 164). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.450 Criteria and Standards for Long-Term Care is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 164–165). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.700 Post-Decision Activity is withdrawn.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 166). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 60—Missouri Health Facilities Review
Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.700 Post-Decision Activity is withdrawn.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 166–167). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars (\$500).

RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 20—DEPARTMENT OF INSURANCE Division 300—Market Conduct Examinations Chapter 2—Record Retention for Market Conduct Examinations

ORDER OF RULEMAKING

By the authority vested in the director of the Missouri Department of Insurance under section 374.045, RSMo 2000, the director amends a rule as follows:

20 CSR 300-2.200 Records Required for Purposes of Market Conduct Examinations **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 439–440). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Missouri Department of Insurance received seven (7) comments on the proposed amendment.

COMMENT: Each person or entity that submitted comments supported the proposed amendment, which deletes the provisions of the regulation relating to third-party vendors and service providers. RESPONSE: The department concurs with the above-referenced comments and has, therefore, not made any changes to the language of the proposed amendment.

his section may contain notice of hearings, correction notices, public information notices, rule action notices, statements of actual costs and other items required to be published in the *Missouri Register* by law.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT Division 100—Division of Credit Unions

APPLICATIONS FOR NEW GROUPS OR GEOGRAPHIC AREAS

Pursuant to section 370.081(4), RSMo 2000, the director of the Missouri Division of Credit Unions is required to cause notice to be published that the following credit unions have submitted applications to add new groups or geographic areas to their membership.

Credit Union	Proposed New Group or Geographic Area		
Southeast Telephone Employees Credit	Persons who live or are employed in the		
Union	Missouri Counties of St. Francois County,		
312 West Main	Ste. Genevieve County, and Madison County		
PO Box 335			
Park Hills, MO 63601			
Anheuser Busch Employees' Credit Union	People who live or work, or legal entities in		
1001 Lynch Street	zip codes 63103, 63110, 63116, 63118, as		
St. Louis, MO 63118	well as legal entities in zip code 63104		

NOTICE TO SUBMIT COMMENTS: Anyone may file a written statement in support of or in opposition to any of these applications. Comments shall be filed with: Director, Division of Credit Unions, PO Box 1607, Jefferson City, MO 65102. To be considered, written comments must be submitted no later than ten (10) business days after publication of this notice in the Missouri Register.

The Secretary of State is required by sections 347.141 and 359.481, RSMo 2000 to publish dissolutions of limited liability companies and limited partnerships. The content requirements for the one-time publishing of these notices are prescribed by statute. This listing is published pursuant to these statutes. We request that documents submitted for publication in this section be submitted in camera ready 8 1/2" x 11" manuscript.

NOTICE OF LIMITED LIABILITY
COMPANY DISSOLUTION
TO ALL CREDITORS AND CLAIMANTS
AGAINST LEVINSON HOLDINGS, L.L.C.

On April 30, 2003, LEVINSON HOLDINGS, L.L.C., a Missouri Limited Liability Company, filed its Articles of Termination with the Missouri Secretary of State. Any claims against the L.L.C., should be sent to Merle L. Silverstein, 7733 Forsyth Blvd., Suite 400, St. Louis, Missouri 63105. All claims must include the name, address and phone number of the claimant; the amount of the claim; the basis of the claim; and the date the claim arose.

All claims must be received by the L.L.C. within three (3) years after publication of this notice. Any claims not received by that date will be barred.

NOTICE TO ALL CREDITORS AND CLAIMANTS OF

CAPITAL CITY HOTEL COMPANY, L.L.C.

You are hereby notified that on March 31, 2003, Capital City Hotel Company, L.L.C., a Missouri limited liability company, agreed to dissolve and wind up the L.L.C. Any claims against the L.L.C. should be sent to RHW Management, Inc. 6704 West 121st Street, Overland Park, Kansas 66209. All claims must include the name, address and phone number of the claimant; amount of the claim; basis for the claim; and documentation of the claim. All claims must be received by the L.L.C. within three (3) years after publication of this Notice. Any claims not received by that date will be barred.

OFFICE OF ADMINISTRATION Division of Purchasing

BID OPENINGS

Sealed Bids will be received by the Division of Purchasing, Room 630, Truman Building, PO Box 809, Jefferson City, MO 65102, telephone (573) 751-2387 at 2:00 p.m. on dates specified below for various agencies throughout Missouri. Bids are available to download via our homepage: www.moolb.state.mo.us.

B1E03314	Safety Supplies: WMD Protective Clothing 6/16/03
B1E03102	Diabetic Supplies Rebate 6/17/03
B1E03312	Raised Flooring: Tate 6/17/03
B3Z03248	Audit Services/Area Agencies 6/17/03
B3Z03260	1115 Demonstration and Senate Bill 632 Evaluation
	6/17/03
B2Z03058	WIC/Data Warehouse Support Services 6/18/03
B1E03318	Foods, Frozen 6/19/03
B3E03258	Drug Testing using Sweat Patch 6/19/03
B1E03315	Chemical Products 6/20/03
B1E03322	Respiratory Protection 6//23/03
B1E03317	Maintenance: Aircraft 6/24/03
B1E03321	Self Contained Breathing Apparatus 6/24/03
B3Z03114	Underground Storage Tank Investigation and Remed-
	iation Services 6/24/03
B3Z03158	Banking Services for WIC 6/24/03
B3Z03253	Fund Administration Services 6/25/03
B3Z03160	Exhibit Production 8/6/03

It is the intent of the State of Missouri, Division of Purchasing to purchase each of the following as a single feasible source without competitive bids. If suppliers exist other than the ones identified, please call (573) 751-2387 immediately.

Secretary of State Knowledge Base (SOSKB) Ongoing Maintenance and Enhancement Services, supplied by Office Automation Solutions.

HemoCue Microcuvettes, supplied by HemoCue, Inc. of Lake Forest, CA.

James Miluski, CPPO, Director of Purchasing MISSOURI REGISTER

Rule Changes Since Update to Code of State Regulations

June 16, 2003 Vol. 28, No. 12

This cumulative table gives you the latest status of rules. It contains citations of rulemakings adopted or proposed after deadline for the monthly Update Service to the *Code of State Regulations*, citations are to volume and page number in the *Missouri Register*, except for material in this issue. The first number in the table cite refers to the volume number or the publication year—26 (2001), 27 (2002) and 28 (2003). MoReg refers to *Missouri Register* and the numbers refer to a specific *Register* page, R indicates a rescission, W indicates a withdrawal, S indicates a statement of actual cost, T indicates an order terminating a rule, N.A. indicates not applicable, RUC indicates a rule under consideration, and F indicates future effective date.

Rule Number	Agency En	nergency	Proposed	Order	In Addition
1 CSR 10	OFFICE OF ADMINISTRATION State Officials' Salary Compensation Schedule				27 MoReg 189
	• •				27 MoReg 1724
1 CSR 20-2.015	Personnel Advisory Board and Division of Personnel		29 MaDag 225	20 MaDag 002	
	or Personner		28 MoReg 225	28 MoReg 983	
	DEPARTMENT OF AGRICULTURE				
2 CSR 30-2.010	Animal Health		28 MoReg 399	This Issue	
2 CSR 30-2.020	Animal Health		28 MoReg 707 28 MoReg 399	This Issue	
2 CSR 50-2.020	Allillai Healtii		28 MoReg 708	This Issue	
			28 MoReg 708		
2 CSR 30-2.040	Animal Health		28 MoReg 400	This Issue	
2 CCD 20 (020	A . 177 14		28 MoReg 711	771 · T	
2 CSR 30-6.020 2 CSR 30-9.020	Animal Health Animal Health		28 MoReg 400 This Issue	This Issue	
2 CSR 30-9.020 2 CSR 30-9.030	Animal Health		This Issue		
2 CSR 70-16.010	Plant Industries		28 MoReg 308		
2 CSR 70-16.015	Plant Industries		28 MoReg 308		
2 CSR 70-16.020	Plant Industries		28 MoReg 309		
2 CSR 70-16.025 2 CSR 70-16.030	Plant Industries Plant Industries		28 MoReg 309 28 MoReg 312		
2 CSR 70-16.035	Plant Industries Plant Industries		28 MoReg 314		
2 CSR 70-16.040	Plant Industries		28 MoReg 314		
2 CSR 70-16.045	Plant Industries		28 MoReg 314		
2 CSR 70-16.050	Plant Industries		28 MoReg 315		
2 CSR 70-16.055	Plant Industries Plant Industries		28 MoReg 315		
2 CSR 70-16.060 2 CSR 70-16.065	Plant Industries Plant Industries		28 MoReg 316 28 MoReg 318		
2 CSR 70-16.070	Plant Industries		28 MoReg 318		
2 CSR 70-16.075	Plant Industries		28 MoReg 318		
2 CSR 80-5.010	State Milk Board		28 MoReg 637		
2 CSR 90-10.040	Weights and Measures		27 MoReg 1161		
2 CSR 90-30.050	Weights and Measures		27 MoReg 1565		
2 555 10 1 111	DEPARTMENT OF CONSERVATION				
3 CSR 10-4.111 3 CSR 10-6.405	Conservation Commission Conservation Commission		This Issue 28 MoReg 851		
3 CSR 10-0.403 3 CSR 10-7.410	Conservation Commission Conservation Commission		This Issue		
3 CSR 10-7.455	Conservation Commission		This Issue		
3 CSR 10-9.110	Conservation Commission		28 MoReg 400	28 MoReg 983	
2 CCD 40 0 FCF			This Issue	20.11.0	
3 CSR 10-9.565 3 CSR 10-10.726	Conservation Commission Conservation Commission		28 MoReg 401 28 MoReg 851	28 MoReg 983	
3 CSR 10-10.720 3 CSR 10-10.732	Conservation Commission Conservation Commission		28 MoReg 852		
3 CSR 10-10.745	Conservation Commission		N.A.	This IssueR	
3 CSR 10-11.160	Conservation Commission		This Issue		
3 CSR 10-11.180	Conservation Commission		This Issue		
3 CSR 10-11.182 3 CSR 10-11.186	Conservation Commission Conservation Commission		This Issue 28 MoReg 402	28 MoReg 983	
J CSK 10-11.100	Consci vation Commission		This Issue	20 MIONES 903	
3 CSR 10-11.205	Conservation Commission		28 MoReg 402	28 MoReg 984	
			This Issue		
3 CSR 10-11.210	Conservation Commission		28 MoReg 403	28 MoReg 984	
3 CSR 10-12.110 3 CSR 10-12.135	Conservation Commission Conservation Commission		This Issue This Issue		
3 CSR 10-12.133 3 CSR 10-12.140	Conservation Commission Conservation Commission		This Issue		
2 2011 10 12.110	The state of the s				
	DEPARTMENT OF ECONOMIC DEVELOPM	ENT			
4 CSR 10-2.022	Missouri State Board of Accountancy		27 MoReg 2266	28 MoReg 984	
4 CSR 30 4.060	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Lan	ndecana Arabitacta	28 MoDea 129	28 MoReg 897	
	Engineers, Froiessional Land Surveyors, and Lan	nuscape Architects	20 MIUNES 120	20 MIUNES 09/	

Missouri Register

Rule Number	Agency Emergency	Proposed	Order	In Addition
CSR 30-11.030	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects	ects 28 MoReg 131	28 MoReg 897	
CSR 30-13.010	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects	ects 27 MoReg 2145	28 MoReg 897	
CSR 30-16.020	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects			
CSR 30-16.030	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects			
CSR 30-16.040	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architecture.			
CSR 30-16.060	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects			
CSR 30-16.070	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects			
4 CSR 30-16.080	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects, Professional Land Surveyors, and Landscape Architects, Professional Land Surveyors, and Landscape Architects, Professional Landscape Architects, Profes			
4 CSR 30-16.090	Missouri Board for Architects, Professional			
4 CSR 30-16.100	Engineers, Professional Land Surveyors, and Landscape Archit Missouri Board for Architects, Professional			
4 CSR 90-13.010	Engineers, Professional Land Surveyors, and Landscape Archit State Board of Cosmetology	ects 28 MoReg 856 28 MoReg 135	28 MoReg 898	
CSR 90-13.050	State Board of Cosmetology	28 MoReg 137	28 MoReg 898	
4 CSR 100	Division of Credit Unions			28 MoReg 814 28 MoReg 914 This Issue
CSR 140-2.055	Division of Finance	28 MoReg 319		
CSR 140-2.140	Division of Finance	28 MoReg 320		
CSR 140-11.010 CSR 140-11.020	Division of Finance Division of Finance	28 MoReg 320R 28 MoReg 320R		
CSR 140-11.020 CSR 140-11.030	Division of Finance	28 MoReg 321		
CSR 140-11.040	Division of Finance	28 MoReg 322		
CSR 145-1.030	Missouri Board of Geologist Registration	28 MoReg 857		
CSR 145-2.030	Missouri Board of Geologist Registration	28 MoReg 857		
CSR 145-2.100 CSR 150-5.100	Missouri Board of Geologist Registration State Board of Registration for the Healing Arts	28 MoReg 857 27 MoReg 2146	28 MoReg 898	
CSR 150-3.100 CSR 150-8.140	State Board of Registration for the Healing Arts	28 MoReg 139	28 MoReg 898	
CSR 165-2.010	Board of Examiners for Hearing Instrument Specialists	28 MoReg 857	20 1/10110g 020	
CSR 165-2.030	Board of Examiners for Hearing Instrument Specialists	28 MoReg 858		
CSR 165-2.060	Board of Examiners for Hearing Instrument Specialists	28 MoReg 858	20.14 B 000B	
CSR 196-1.010 CSR 200-4.010	Landscape Architectural Council State Board of Nursing	27 MoReg 2146R 28 MoReg 541	28 MoReg 899R	
CSR 200-4.010 CSR 200-4.200	State Board of Nursing State Board of Nursing	27 MoReg 2150	28 MoReg 899	
CSR 220-2.010	State Board of Pharmacy	28 MoReg 543	20 1/10/10/2	
CSR 220-2.020	State Board of Pharmacy	28 MoReg 9	28 MoReg 899	
CSR 220-2.030	State Board of Pharmacy	27 MoReg 2268	28 MoReg 900	
CSR 220-2.130	State Board of Pharmacy	28 MoReg 403	20 MaDaa 000W	
CSR 220-2.190 CSR 220-2.200	State Board of Pharmacy State Board of Pharmacy	27 MoReg 2268 28 MoReg 10R	28 MoReg 900W This IssueR	
CSR 220-2.200	State Board of Filarmacy	28 MoReg 10	This Issue	
CSR 220-2.400	State Board of Pharmacy	28 MoReg 20	This Issue	
CSR 220-2.650	State Board of Pharmacy	28 MoReg 21	28 MoReg 900	
CSR 220-2.700	State Board of Pharmacy	27 MoReg 2268	28 MoReg 900	
CSR 220-2.900 CSR 230-2.070	State Board of Pharmacy State Board of Podiatric Medicine	28 MoReg 543 28 MoReg 139	28 MoReg 900	
CSR 235-1.020	State Committee of Psychologists	28 MoReg 545	20 Moreg 700	
CSR 240-3.180	Public Service Commission	28 MoReg 1024		
4 CSR 240-3.250	Public Service Commission	28 MoReg 1028		
CSR 240-20.065	Public Service Commission	28 MoReg 711	29 MaDag 1049	
4 CSR 240-31.010 4 CSR 240-31.050	Public Service Commission Public Service Commission	27 MoReg 2159 27 MoReg 2160	28 MoReg 1048 28 MoReg 1048	
CSR 240-31.060	Public Service Commission	27 MoReg 2163	28 MoReg 1049	
CSR 240-31.065	Public Service Commission	27 MoReg 2166	28 MoReg 1049	
CSR 240-33.070	Public Service Commission	27 MoReg 2169	28 MoReg 1050	
4 CSR 240-40.018 4 CSR 240-120.085	Public Service Commission Public Service Commission	28 MoReg 1032 28 MoReg 1032		
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4 CSR 240-121.065	Public Service Commission	28 MoReg 1035		
4 CSR 240-123.030	Public Service Commission 28 MoReg 288	28 MoReg 549	This Issue	
CSR 240-123.095	Public Service Commission State Committee for Social Workers	28 MoReg 1037	20 MaDaa 000	
4 CSR 263-1.010	State Committee for Social Workers State Committee for Social Workers	27 MoReg 2169 27 MoReg 2170	28 MoReg 900 28 MoReg 901	
4 CSR 263-1 015	Same Committee for Social Workers			
	State Committee for Social Workers	2/ MoReg 21/0	28 Mokeg 901	
4 CSR 263-1.015 4 CSR 263-1.025 4 CSR 263-1.035 4 CSR 263-2.020	State Committee for Social Workers State Committee for Social Workers State Committee for Social Workers	27 MoReg 2170 27 MoReg 2170 27 MoReg 2171	28 MoReg 901 28 MoReg 901 28 MoReg 902	

Rule Changes Since Update

	Agency Emerg	gency Proposed	Order	In Addition
4 CSR 263-2.030	State Committee for Social Workers	27 MoReg 2171	28 MoReg 902	
4 CSR 263-2.031	State Committee for Social Workers	27 MoReg 2172	28 MoReg 903	
4 CSR 263-2.032	State Committee for Social Workers	27 MoReg 2173	28 MoReg 903	
CSR 263-2.045	State Committee for Social Workers	27 MoReg 2174	28 MoReg 904	
1 CSR 263-2.047	State Committee for Social Workers	27 MoReg 2174	28 MoReg 904	
1 CSR 263-2.050 1 CSR 263-2.052	State Committee for Social Workers State Committee for Social Workers	27 MoReg 2178 27 MoReg 2178	28 MoReg 904 28 MoReg 905	
CSR 263-2.060	State Committee for Social Workers	27 MoReg 2178 27 MoReg 2182	28 MoReg 905	
CSR 263-2.062	State Committee for Social Workers	27 MoReg 2182 27 MoReg 2182	28 MoReg 905	
CSR 263-2.070	State Committee for Social Workers	27 MoReg 2186	28 MoReg 906	
CSR 263-2.072	State Committee for Social Workers	27 MoReg 2186	28 MoReg 906	
CSR 263-2.075	State Committee for Social Workers	27 MoReg 2186	28 MoReg 906	
4 CSR 267-4.020	Office of Tattooing, Body Piercing			
	and Branding 28 MoF	Reg 947		
CSR 270-1.021	Missouri Veterinary Medical Board	28 MoReg 859		
CSR 270-1.031	Missouri Veterinary Medical Board	28 MoReg 861		
CSR 270-2.051	Missouri Veterinary Medical Board	28 MoReg 861		
CSR 270-4.031	Missouri Veterinary Medical Board	28 MoReg 861		
CSR 270-4.042	Missouri Veterinary Medical Board	28 MoReg 861		
4 CSR 270-4.060	Missouri Veterinary Medical Board	28 MoReg 862		
CSR 270-7.010	Missouri Veterinary Medical Board	28 MoReg 864		
	DEPARTMENT OF ELEMENTARY AND SECON	DARY EDUCATION		
5 CSR 30-4.010	Division of Administrative and Financial Services	28 MoReg 322R		
5 CSR 50-310.010	Division of School Improvement	28 MoReg 1039R		
CSR 50-340.110	Division of School Improvement	28 MoReg 1039		
CSR 50-340.150	Division of School Improvement	27 MoReg 2193	28 MoReg 909	
5 CSR 50-340.200	Division of School Improvement	28 MoReg 1040	8	
CSR 50-350.015	Division of School Improvement	28 MoReg 1042R		
5 CSR 50-350.040	Division of School Improvement	28 MoReg 640		
5 CSR 50-355.100	Division of School Improvement	28 MoReg 323		
5 CSR 50-360.010	Division of School Improvement	28 MoReg 1042R		
5 CSR 50-370.010	Division of School Improvement	28 MoReg 1042R		
5 CSR 60-900.050	Vocational and Adult Education	This Issue		
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9 CSR 10-7.090	Director, Department of Mental Health	28 MoReg 848	28 MoReg 873		
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O CSR 30-3.032	Certification Standards	28 MoReg 848	28 MoReg 874		
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10 CSR 10-2.070	Air Conservation Commission		28 MoReg 551		
0 CSR 10-2.340	Air Conservation Commission		28 MoReg 325		
0 CSR 10-2.390	Air Conservation Commission		28 MoReg 552		
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0 CSR 60-2.015	Public Drinking Water Program		28 MoReg 735		
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0 CSR 60-4.030	Public Drinking Water Program		28 MoReg 737		
0 CSR 60-4.040	Public Drinking Water Program		28 MoReg 739		
0 CSR 60-4.050	Public Drinking Water Program		28 MoReg 739		
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11 CSR 40-2.030	Division of Fire Safety		28 MoReg 645R		
11 CSR 40-2.040	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-2.050	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-2.060	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-5.020	Division of Fire Safety		28 MoReg 27	28 MoReg 910	
11 CSR 40-5.050	Division of Fire Safety		28 MoReg 27	28 MoReg 910	
11 CSR 40-5.065	Division of Fire Safety		28 MoReg 27	28 MoReg 910	
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11 CSR 40-6.010	Division of Fire Safety		28 MoReg 973	20 1/10108 /11	
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11 CSR 40-6.040	Division of Fire Safety		28 MoReg 977		
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11 CSR 45-5.200	Missouri Gaming Commission		28 MoReg 404		
11 CSR 45-9.030	Missouri Gaming Commission		This Issue		
11 CSR 45-10.030	Missouri Gaming Commission		28 MoReg 649		
11 CSR 45-30.540	Missouri Gaming Commission		This Issue		
11 CSR 45-30.550	Missouri Gaming Commission	20 MaDaa 620	This Issue		
11 CSR 50-2.430 11 CSR 50-2.440	Missouri State Highway Patrol Missouri State Highway Patrol	28 MoReg 629 28 MoReg 629	28 MoReg 649 28 MoReg 650		
11 CSR 75-13.010	Peace Officer Standards and Training		28 MoReg 1043		
11 CSR 75-14.030	Peace Officer Standards and Training		28 MoReg 1043		
11 CSR 75-14.080	Peace Officer Standards and Training		28 MoReg 1044		
12 CSR 10-2.045 12 CSR 10-23.190	Director of Revenue Director of Revenue		27 MoReg 2203 This Issue	28 MoReg 991	
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12 CSR 10-23.446	Director of Revenue		28 MoReg 981		
12 CSR 10-24.140	Director of Revenue		28 MoReg 404	20 M D 012D	
12 CSR 10-26.100 12 CSR 10-26.180	Director of Revenue Director of Revenue		28 MoReg 150R This Issue	28 MoReg 912R	
12 CSK 10-20.160	(Changed from 12 CSR 10-23.190)		Tills Issue		
12 CSR 10-110.900	Director of Revenue		28 MoReg 881		
12 CSR 10-111.010	Director of Revenue		28 MoReg 886		
12 COR 10 III.010	DEPARTMENT OF SOCIAL SER'	VICES	20 110105 000		
13 CSR 40-30.020	Division of Family Services	27 MoReg 2265	27 MoReg 2299	28 MoReg 988	
13 CSR 40-31.025	Division of Family Services		28 MoReg 34		
13 CSR 70-1.020	Division of Medical Services		28 MoReg 405		
13 CSR 70-3.065	Division of Medical Services	28 MoReg 288	28 MoReg 327		28 MoReg 592
13 CSR 70-4.040	Division of Medical Services		28 MoReg 1044		
13 CSR 70-10.015	Division of Medical Services	28 MoReg 103	28 MoReg 150	28 MoReg 988	
13 CSR 70-15.010	Division of Medical Services		28 MoReg 560		
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13 CSR 73-1.010	Division of Medical Services Missouri Board of Nursing Home Administrators (Changed to 19 CSR 73-1.010)		28 MoReg 412		
13 CSR 73-2.015	(Changed to 19 CSR /3-1.010) Missouri Board of Nursing Home Administrators (Changed to 19 CSR 73-2.015)		28 MoReg 412		
13 CSR 73-2.020	Missouri Board of Nursing Home Administrators (Changed to 19 CSR 73-2.020)		28 MoReg 412		
13 CSR 73-2.025	Missouri Board of Nursing Home Administrators (Changed to 19 CSR 73-2.025)		28 MoReg 417		
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13 CSR 73-2.051	Missouri Board of Nursing Home Administr (Changed to 19 CSR 73-2.051)	rators	28 MoReg 419		
13 CSR 73-2.055	Missouri Board of Nursing Home Administr	rators	28 MoReg 419		
13 CSR 73-2.060	(Changed to 19 CSR 73-2.055) Missouri Board of Nursing Home Administr	rators	28 MoReg 420		
13 CSR 73-2.080	(Changed to 19 CSR 73-2.060) Missouri Board of Nursing Home Administr (Changed to 19 CSR 73-2.080)	rators	28 MoReg 420		
13 CSR 73-2.085	Missouri Board of Nursing Home Administr	rators	28 MoReg 421		
13 CSR 73-2.090	(Changed to 19 CSR 73-2.085) Missouri Board of Nursing Home Administr	rators	28 MoReg 421		
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Department of Transportation Missouri Highways and Transportation Commission 7 CSR 10-3.040 Division of Relocation Costs	. Next Issue	February 26, 2004 February 26, 2004
Department of Labor and Industrial Relations Division of Employment Security 8 CSR 10-3.130 Direct Deposit of Unemployment Benefits	28 MoPeg 0/8	October 27, 2003
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9 CSR 45-5.060 Procedures to Obtain Certification	. 28 MoReg 629	.September 22, 2003
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03-02	Establishes the Division of Family Support in the Dept. of Social Services	February 5, 2003	28 MoReg 298
03-03	Establishes the Children's Division in the Dept. of Social Services	February 5, 2003	28 MoReg 300
03-04	Transfers all TANF functions to the Division of Workforce Development	February 5, 2003	28 MoReg 302
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03-07	Creates the Commission on the Future of Higher Education	March 17, 2003	28 MoReg 631
03-09	Lists Governor's Staff Who Have Supervisory Authority Over Departments	March 18, 2003	28 MoReg 633
03-10	Creates the Missouri Energy Policy Council	March 13, 2003	28 MoReg 634
03-11	Creates the Citizens Advisory Committee on Corrections	April 1, 2003	28 MoReg 705
03-12	Declares Disaster Areas due to May 4 Tornadoes	May 5, 2003	28 MoReg 950
03-13	Calls National Guard to Assist in Areas Harmed by the May 4 Tornadoes	May 5, 2003	28 MoReg 952
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